Towards digital twinning for additive manufacturing of medical implants

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DECLARATION

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ABSTRACT

The level of complexity of a business increases as additive manufacturing (AM) is introduced into their process chains. As AM of medical implants is becoming more popular, more complexity within process chains arises. As more intricate technologies are used, more steps are added to the process chain, more workers and supervision are needed, and the flawless flow of the process chain becomes essential. As more activities occur within the business, time becomes an essential resource that needs to be allocated optimally. Finding a tool to help with the optimisation of resources can put a business on the right path.

In this study, an intensive literature review was conducted to inform the researcher on the day-to-day operations at the Centre for Rapid Prototyping and Manufacturing (CRPM) and how it works. An in-depth investigation of the process chain at CRPM was furthermore done to identify problem areas. By studying the process chain thoroughly, it was possible to gain in-depth insight into what the as-is state and the desired to-be state were. The optimisation of time was identified as one desired goal for the to-be state. As time is a limiting factor that cannot be replaced or stored, finding a bridge to fill the gap between current and desired states becomes even more important. Hence this investigation into digital twinning.

Digital twins are virtual replicas of businesses, processes, or systems. The steps needed to develop a digital twin were researched. Two basic digital twin examples were developed and illustrated how the user can adjust data and the process to solve problems. The digital twin examples include a basic costing system that can predict what the total cost of a certain product will be. Whether or not to use digital twin technology within a business can be a daunting decision; therefore, a decision-making tool was suggested to help the business decide when to use a digital twin and when other quality tools would be more appropriate. The decision-making tool was applied to CRPM and showed that a digital twin is a better fit than other quality tools in some instances. Digital twins are adaptable and can therefore be adjusted and changed to suit the needs of the business. They are also found to be valuable planning tools that can aid in the optimisation of time usage by ensuring that a business knows what will happen in each type of situation. Changes to the process chain can be made and the effects were seen without having to implement the changes physically, thereby optimising time usage at CRPM as no time is wasted with unnecessary processes or planning. This study concludes that a digital twin can act as a possible tool to aid in the optimisation of time usage in AM businesses.

OPSOMMING

Met toename in die gebruik van laagvervaardiging in die proseskettings van besighede, verhoog die vlak van kompleksiteit. Omdat die laagvervaardiging van mediese inplantings meer populêr word, raak die kompleksiteit van prosesse ŉ groter uitdaging. Met die gebruik van meer ingewikkelde tegnologie word al hoe meer stappe in die prosesketting voorgestel, daarom word meer werkers en toesig benodig en word die foutlose vloei van die prosesketting uiters belangrik. Meer aktiwiteite beteken die gebruik van meer tyd, en die optimalisering van die beskikbare tyd word noodsaaklik. Daarom word ŉ hulpbron benodig om te help met die optimalisering van bronne.

In hierdie studie is ŉ intensiewe literatuurstudie gedoen en ŉ goeie agtergrond gegee oor die dag-tot-dag werksaamhede van CRPM. ŉ In-diepte studie is verder gedoen oor die prosesketting by CRPM, wat ŉ aantal probleemareas geïdentifiseer het. Deur die prosesketting deeglik te bestudeer, kon die navorser agterkom wat die huidige toestand en die gewenste toekomstige toestand van CRPM was. Die optimalisering van tydsgebruik is as een van die gewenste toestande geïdentifiseer. Aangesien tyd ŉ beperkte bron is, word die aanvraag om die gaping tussen nou en die toekoms te brug al hoe belangriker, daarom het hierdie ondersoek oor digitale tweelinge begin. Digitale tweelinge is virtuele replikas van besighede, prosesse of sisteme. Navorsing is gedoen om die stappe vir die ontwikkeling van ŉ digitale tweeling te identifiseer. Twee basiese digitale tweeling voorbeelde is ontwikkel en het geïllustreer hoe die gebruiker data en die proses kan aanpas om probleme op te los. Die digitale tweeling voorbeelde sluit ŉ basiese koste-model in wat kan voorspel wat die totale koste van ŉ bepaalde produk gaan wees. Dit is nie altyd maklik om te besluit om ŉ digitale tweeling te gebruik nie, en daarom is ŉ besluitnemingsproses voorgestel om die gebruiker te help om te kan besluit wanneer ŉ digitale tweeling gebruik moet word en wanneer ander kwaliteitsgereedskap meer toepaslik sou wees. Die besluitnemingsproses is toegepas op CRPM se prosesketting en het aangedui dat ŉ digitale tweeling in sommige gevalle beter werk. Digitale tweelinge is aanpasbaar en kan verander om die behoeftes van die besigheid te akkommodeer. Hulle is ook waardevolle hulpmiddels in beplanning en kan help om te verseker dat tydsgebruik geoptimaliseer word deur seker te maak dat besighede vooraf weet wat in elke tipe situasie sal gebeur. Aangesien digitale tweelinge replikas van die proses, sisteem of subsisteem is, elimineer dit die onbekende, wat help met die beplanning van prosesse en tydsgebruik. Veranderinge kan gemaak word en die effekte daarvan kan gesien word sonder dat die besigheid fisies enige verandering implementeer. Sodoende word tydsgebruik by CRPM geoptimaliseer en word geen tyd gemors op onnodige prosesse of beplanning nie. Hierdie studie sluit af deur te bevestig dat digitale tweelinge ŉ voldoende hulpmiddel is om tydsgebruik in laagvervaardigingbesighede te optimaliseer.

ACKNOWLEDGEMENTS

The successful completion of this study would not have been possible without the valuable contributions of the following persons. I would therefore like to express my sincere gratitude to:

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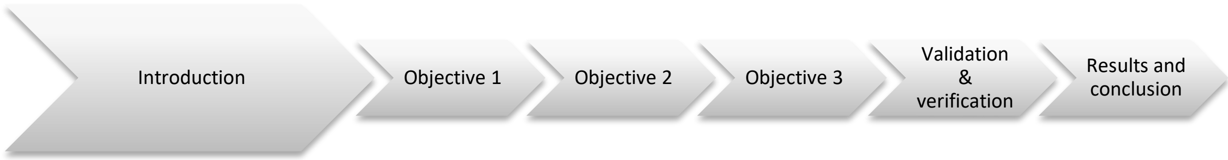
ABBREVIATIONS

ABC	Activity-based costing
AI	Artificial intelligence
AM	additive manufacturing
ASTM	American Society of Testing Materials
CAD	computer- aided design
CFD	computational fluid dynamics
CIM	computer-integrated manufacturing
CNC	computerised numerical control
CRPM	Centre of Rapid Prototyping
CSV	comma separated values
CT	computed tomography
CUT	Central University of Technology
DT	Digital Twin
EPC	Event-driven process chains
ERP	enterprise resource planning
FEA	finite element analysis
ICT	information communication technology
IoT	Internet of things
IT	information technology
KPI	key performance indicator
MES	manufacturing execution systems
ML	machine learning
MRI	magnetic resonance imaging
MTBF	mean time between failures
MTTR	mean time to repair
OEM	original equipment manufacturers

PLM	product lifecycle management
PM	project manager
ROI	return on investment
SA	South Africa
SAJIE	South African Journal of Industrial Engineering
SOP	standard operating procedures
STL	standard triangle language
SWOT	strengths, weaknesses, opportunities and threats
TDABC	time-driven activity-based costing
TKR	total knee replacement
VUT	Vaal University of Technology

1 CHAPTER 1 – INTRODUCTION



This chapter serves as an introduction to the study. It provides a background on the research topic and an explanation of how the topic was decided on and what the project's general purpose will be. The problem, research question and aim are then described in detail, as well as three objectives. The scope of the research, its limitations and the assumptions that were made during the study are then discussed, as well as the methodology followed during the study and the research design. Finally, a roadmap for the rest of this document is provided.

1.1 Project background and origin

The Centre for Rapid Prototyping and Manufacturing (CRPM) specializes in the additive manufacturing (AM) of medical implants. The CRPM is situated at the Central University of Technology (CUT) in Bloemfontein in the Free State (CRPM, 2018). The company was established in 1997 and focuses on research and commercial work (Anderson, 2018). It manufactures a range of products using AM technologies, including medical implants: preoperative models, cutting guides, implants, spinal cages, screws, dental implants (used to help with the insertion of new teeth or give shape to the mouth after extensive removal surgery), as well as other industrial parts. Although the company additively manufactures many different parts, the focus will be placed on medical implants. These medical implants are manufactured for patients undergoing surgeries to remove parts of their facial bones, due to extensive cancerous growths or any other circumstance that caused them to lose a part of their facial structure. The implants need to measure up to the exact specifications provided by the computed tomography (CT) or magnetic resonance imaging (MRI) scans. If an implant does not meet specifications, it must be redone, and the patient is left with a malformed face or surgeons need to quickly make plans to adjust the implant. Both scenarios can cause severe pain for the patient as well as extra theatre time, increasing the overall cost. It is important to note that most of the patients treated by CRPM come from poor, rural areas and do not have medical aids or any funds to cover medical costs. CRPM receives a yearly grant which they use for the treatment of these patients.

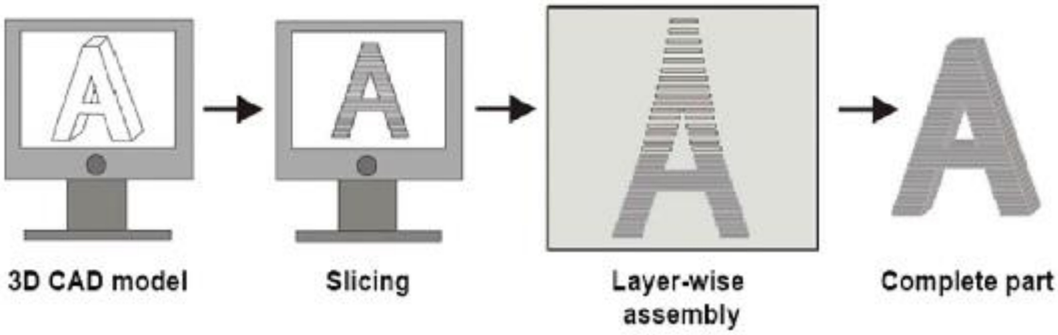


Figure 1.1: Basic flow diagram of the AM process (Koren & Shpitalni, 2010)

Figure 1.1 shows a basic example of how the AM process works. Each product produced by CRPM is made to fit the concerned patient's facial bone structure precisely. The first step will be to take the CT scans and design a 3D CAD model of the scan. The design is then put into a slicing program, to be additively manufactured using layer assembly, and, finally, the complete part is produced. A preoperative model is additively manufactured using magnetic resonance (MRI), as well as CT scans of the patient's face and the affected area. Once the preoperative model is completed, it is sent to the surgeon who adjusts and forms the model as he/she prefers by using wax. The adjusted model is then reverse engineered to create a digital model. The digital model is made using Geomagic software, including computer-aided design (CAD) drawings, creating a customised implant. Since each patient's case is different, each implant will be different in shape, size, and complexity level (De Beer et al., 2016).

The production process at a company like CRPM must flow flawlessly to ensure that all work happens at the right time and right pace for the end product to be on time and of desired quality. Bottlenecks are one factor that can cause major problems for a company like CRPM: if work is backed up, the implant will not be ready in time for surgery and the patient will have to wait longer – this can lead to an enlargement of the cancerous growth and thus the original scans will not be sufficient any longer. The process will have to be started all over again and valuable time and money will be wasted. Because CRPM works on more than one project simultaneously, a ripple effect will be caused throughout the company if there is a pause or a restart on one project, causing other projects to become backed up as well. This is mainly due to the amount of printing space available; each machine can only print at a certain speed and a certain amount of product at a time, and the number of machines in operation at the time also influences production.

1.2 Description of the problem

1.2.1 Problem statement

Businesses' complexity levels increase as AM is introduced into their process chains. The AM of medical implants is becoming more popular, making the increasing complexity levels of the business a challenge that needs to be dealt with. As more intricate technologies are used, more steps are added to the process chain, more workers and more supervision are needed. The flawless flow of the process chain becomes essential. As more activities occur within the business, time becomes an essential resource that needs to be allocated optimally. Finding a tool to help with the optimisation of resources can already push businesses in the right direction.

This research will thus focus on a method where the optimal allocation of resources can be obtained by adjusting the resources as time goes on and by observing the effects that these adjustments have on the process chain. Adjustments that are physically made to the business or made while the business runs, can cause unaccounted for problems and difficulties. These problems could cost the business money and time and thus, planning for these adjustments becomes a critical step. Ideally, a business should be able to adapt to any unexpected problems that arise. The problem is that the optimisation of the business process chain cannot happen without possibly having detrimental effects on the business and planning for change can become a tedious process.

1.2.2 Research question and aim

The research question is qualitative and will be investigated using theory and practical knowledge. The main research question which acts as a possible solution to the problem statement is:

Is a digital twin a possible tool to optimise time for an AM business?

Digital twins are used to computerise situations, thus parameters of the business can be changed, adjusted, added, or taken away and the effects can be viewed without the physical effects being implemented. Resource allocation can be adjusted; this includes how time, money, worker allocation, and many more are used.

The research will focus on AM businesses because they are profit driven. Time optimisation is the end goal because when time is optimised, more work can be done, and profits earned will be higher. Although quality and money usage are equally important parameters, the research will mainly focus on time optimisation.

This research will cover the foundation of a digital twin which can be later expanded to form more comprehensive and detailed digital twins. The main aim of the study is to use a systematic engineering approach to aid with the identification and implementation of digital twins for an AM business, to optimise time and thereby increase global competitiveness.

1.2.3 Research objectives

The systems engineering approach used during this study corresponds with the Innovation Road Map W-model, which is based on the V-model but implements evaluation throughout (Converso, De Vito & Santillo, 2007). In accordance with the W-model, the following objectives had to be met:

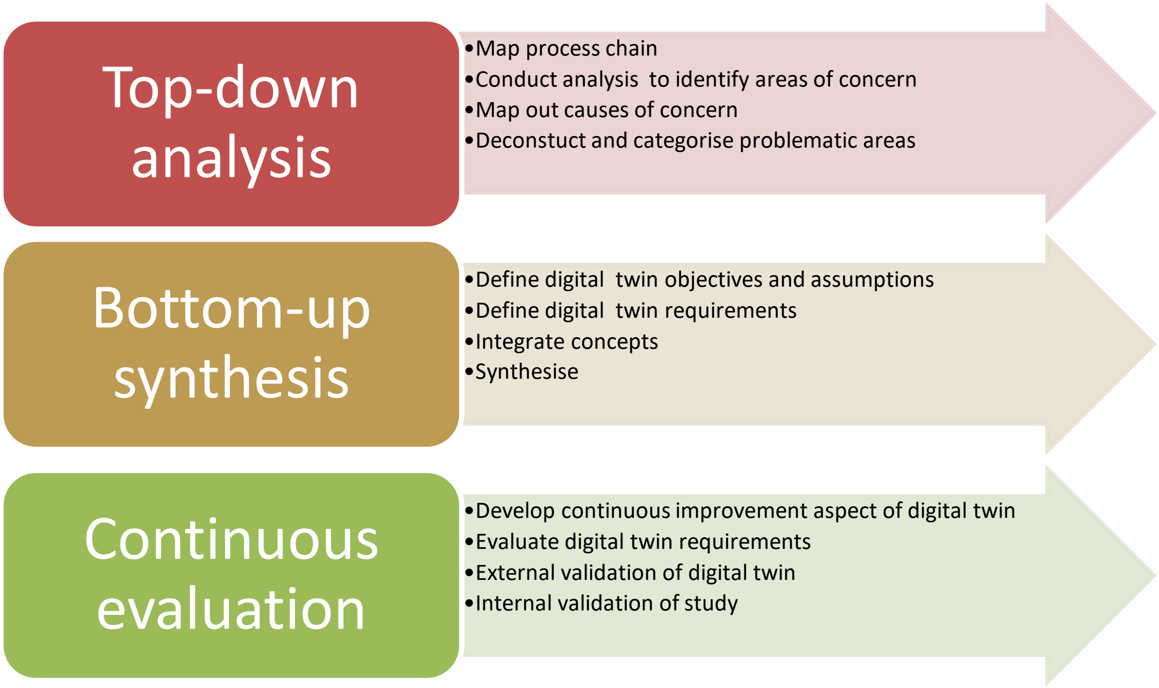


Figure 1.2: Research objectives

The focus of this study is to optimise time usage in the process chain but also to discover better strategies for the allocation of parameters. To ensure the success of this research, each objective needs to be met. Each objective is measurable and contributes to the conclusion of this project. By answering the above research questions, the objectives of this study are:

Objective 1: Top-down analysis of the process chain at CRPM

The research problem must be broken down into its basic components for a comprehensive understanding of its extent. The process chain is a list or number of steps that is used every time that a maxillofacial implant is manufactured. Understanding each step in the process chain ensures well-rounded knowledge of how CRPM functions. This makes it easier to identify where problems may occur, which steps could be adjusted, and where the most time and money are being spent. An important question to ask here is: how can I improve the current system and process chain? A SWOT analysis and as-is vs. to-be chart will be used to identify where major problems occur.

Objective 2: Bottom-up synthesis used to develop a digital twin

The deconstructed problems in Objective 1 should be used to develop and implement steps to aid users in developing and implementing digital twins as a tool to aid time optimisation in AM businesses.

During the synthesis process, the digital twin objectives, assumptions, and requirements must be defined, followed by the integration and synthesis of various components. Addressing this objective will show the development of basic digital twin examples and how it connects to CRPM. The digital twins will aid as a time optimisation tool.

Objective 3: Integrating the digital twin for business

In accordance with the W-model, the digital twin requirements should be evaluated both before and after the synthesis process. Objectives 1 and 2 are used to simplify the digital twin development process and to link it to CRPM. The digital twin uses information previously gathered to strengthen the research and to build on what has already been found. To ensure that a digital twin is the most suitable tool for CRPM to use, a decision-making tool will be proposed.

1.2.4 Scope

The aim of this research is to gain a better understanding of whether digital twinning can act as a possible optimisation tool for the AM business. Since AM businesses cover various areas, focus will be placed on the AM of medical implants. Furthermore, while the digital twin will be largely applicable to many AM products or processes, it will only be tested on the CRPM situation. As such, the digital twin will require future expansion. Also, due to the competitive nature of the field and the case study being applied to an existing company, certain data was not allowed to be disclosed to the researcher regarding specific times and costs. In these instances, the data used was random and for explanatory purposes only.

The digital twin will be represented theoretically and by means of two AnyLogic examples which can act as foundation for further research or more extensive digital twin models. To be able to answer the research question, it is necessary to study process chains, how digital twins work, including their building blocks and whether they can act as optimisation tools.

1.2.5 Limitations and assumptions

Since AM is an emerging technology, there are certain limitations to the extent that it can be studied. This includes the following:

- AM technologies are ever evolving and changing; thus the framework will only cover certain AM processes.
- Due to budget and technological constraints, available technologies had to be used, which may not be as detailed as desired. Basic examples were also used.
- Due to the lack of knowledge and the propriety nature of the processes, the full implementation of the digital twin cannot be done in this study.

1.3 Methodology

The research is predominantly qualitative, based on expert interviews, and follows a systems engineering approach.

1.3.1 Thesis methodology

This thesis follows a step-by-step approach, where the next step can only be started once the previous step has been completed. The research will follow the W-model, where constant evaluation will take place. Change management strategies will be employed throughout the thesis to ensure the successful implementation of the future digital twin. Different parameters must be tested in order to see what the system's sensitivity is. The W-approach will consist of a comprehensive literature review, a comprehensive study of the process chain that will be conducted at CRPM, as well as the development of the digital twin with continuous evaluation. A decision-making tool will confirm the need for the digital twin and will be continuously used to evaluate that the need remains.

1.3.2 Literature analysis methodology

Since digital twinning is a new and evolving concept, the amount of literature available at the start of the study was limited. Research was done on concepts that link to digital twins and that can affect a digital twin. The main concern for the study was to identify whether a digital twin could aid in the optimisation of time for an AM business. From the start, it was clear that there were only a few formal published artefacts regarding digital twinning in this sector. This can be viewed as a potential weakness for this thesis which relied mainly on published work, expert opinion, and internet sources.

1.4 Research design

As shown in Figure 1.3, the research design is divided into five different steps, each dependent on the information gathered in the previous step. The first step is to identify, understand and define the problem. This was done by conducting a thorough literature study of the field, taking into account both the available theoretical and practical knowledge.

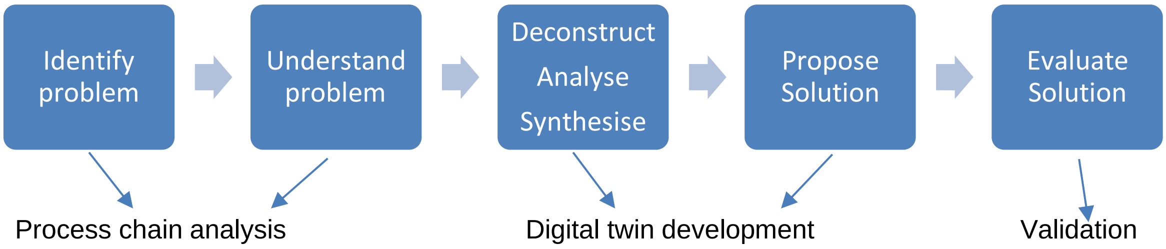
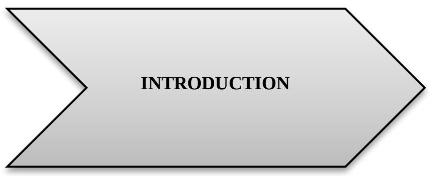


Figure 1.3: Research design outline

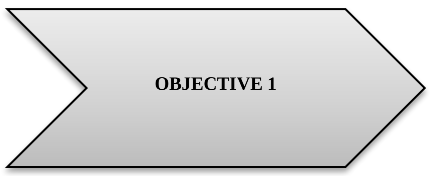
A part of the literature review was to gain a better understanding of the problem and a different part was to determine the problem's key fields of concern or risks or focus areas. Finally, the third step entailed deconstructing the problem into key concepts, analysing those concepts, and synthesising them into a problem solution in the form of a digital twin. The digital twin is then proposed as a solution to the research problem and, finally, evaluated to determine its effectiveness and relevance in addressing the problem.

The research project was designed in such a way that the student first had to investigate and understand the process chain at CRPM. Research will be conducted into the steps involved, as well as possible problematic areas. Following this, the goal was to understand everything that went into the design and development of a digital twin. The knowledge gained was then used to develop a digital twin. Finally, the knowledge gained in Objectives 1 and 2 was used to integrate the digital twin for business. Knowledge that was obtained during the first two objectives had to be understood properly and applied to Objective 3.

1.5 Project roadmap



Chapter 1 is the introductory chapter where the reader is introduced to the research problem and background, as well as how the researcher will attempt to answer the research question.



Chapter 2 explains Objective 1, where a top-down analysis method is used to investigate the process chain and identify problematic areas. The problem areas will be investigated to find a possible bridge between the as-is and to-be states.

OBJECTIVE 2

Chapter 3 investigates Objective 2, which is dependent on Objective 1, and will use a bottom-up approach based on the knowledge gained in Objective 1 to attempt to develop the suggested bridge mentioned in Objective 1.

OBJECTIVE 3

Chapter 4 explores Objective 3, which is dependent on Objectives 1 and 2. Continuous evaluation will be used to attempt to test the digital twin that is developed in Objective 2 to ensure that it is suitable and answers the research question.

VERIFICATION & VALIDATION

Chapter 5 is made up of Verification and Validation. The researcher now confirms that the research question is answered and uses different methods to prove this.

CONCLUSION

Chapter 6 concludes the entire project and gives a critical overview of what could have been done differently and where research gaps lie for future researchers.

1.6 Project timeline

This project was started on 1 February 2019 and completed on 15 September 2021.

1.7 Conclusion

The research question that this research looks at is:

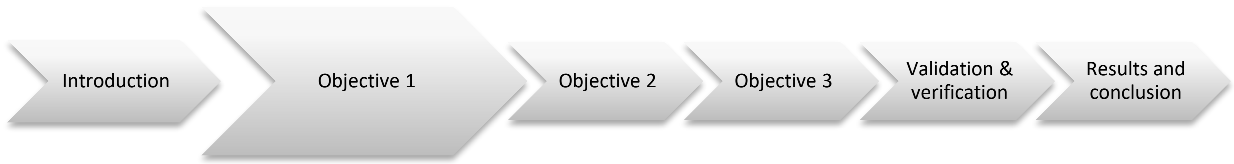
Is a digital twin a suitable tool to optimise time for an AM business?

The objectives identified to answer the research question are:

1. Top-down analysis of the process chain at CRPM, which will be used to investigate and identify risks and possible solutions to these risks.
2. Develop a digital twin to investigate business parameters.
3. Integrate the digital twin for business.

Each chapter will attempt to discuss the entirety of each objective. The first chapter discusses the project roadmap for this research. It gives an overview of what the researcher attempts to achieve with this thesis. The industrial partner that is worked with is introduced.

2 CHAPTER 2 – OBJECTIVE 1: TOP-DOWN ANALYSIS OF THE PROCESS CHAIN AT CRPM



Chapter 2 describes Objective 1 – which is to analyse the process chain at CRPM – by doing a literature review and outlining the results. Objective 1 is based on the research question, which the researcher will attempt to answer by discussing several research articles. A methodology is formed for this objective, based on the literature review. Following the predetermined method, the results are described, and several recommendations are made based on the results.

2.1 Literature study

The exploration of the literature starts with investigating the definition of AM and how it plays a role regarding medical implants. It also seeks to define and investigate what a process chain is, how change is implemented and the role it plays in an AM business, as well as possible problem areas.

2.1.1 Process chain vs. value chain

Value chain maps provide a high-level view of a company's flow of goods and services. Value chains represent how an organization transforms raw materials into value for its customers at a high level. Process chains provide a representation of the inputs, outputs, and decisions that occur at the task and/or activity level. The focus of the research will be on the process chain as the research question aims at finding a tool to optimise the time of an AM process, which includes the decisions that need to be made at each process and the subsystems that need to be considered. Should problem areas be identified in the process chain and be improved on, the optimisation of time will occur.

2.1.2 Defining and understanding a process chain

According to Jacobs and Chase (2014), a process is any part of an organisation that takes inputs and transforms them into outputs. The outputs produced are of greater value to the organisation than the original inputs. Furthermore, a process consists of multiple-stage processes with multiple group activities. A project process aims at achieving a precisely defined objective for a known customer in limited time. A new-product project is market-oriented and subsequent to continuous production. A new-product project is precise in terms of deadlines, cost, and quality (Hallikas et al., 2004).

Kim (2006) defines the process chain as a “flexible and efficient chain, network, or web of related firms that work together to achieve global optimisation of a common performance goal for a total supply chain”. According to Jacobs (2014), the process chain is compiled of a sequence of processes that are scheduled to wait in the background for an event to occur. These processes can then trigger separate events that start new processes. Porter’s competitive advantage strategy (Porter, 1980) focuses on the dimensions of quality, speed, innovation, and cost, thus being the profit ratio. Competitive advantage implies that the organisation offers superior customer value and indicates the distinctive differences between an organisation and its competitors. To ensure that a competitive advantage can be reached, the process chain needs to be optimised.

Customisation is a way of creating value for customers and impacts the process chain. As a product becomes more customised, the price rises (Bernhardt & Liu, 2007). Customisation in the medical field involves products and equipment being 3D printed. Medically customised products are the adaptation of the product to the specific human anatomy rather than the situation where software is personalised for a device. Mass customisation in the medical field is divided into medical devices that do not interact chemically with the body, and implantable parts where the part is expected to interact with the biological system (Dalgarno et al., 2006). As customisation takes place, the steps included in a process chain become more complex.

2.1.3 **Additive manufacturing (AM)**

According to the American Society for Testing Materials (ASTM), AM is defined as the process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies. In a product development context, the term, rapid prototyping, was widely used to describe technologies that created physical prototypes directly from digital data (Horn & Harrysson, 2012). However, the term overlooks the basic principle of these technologies in that they all fabricate parts using an additive approach. The basic principle of AM technology is that a model that is initially generated using a three-dimensional computer-aided design (3D CAD) system can be fabricated directly. Most manufacturing processes require a careful and detailed analysis of the part geometry to determine things like the order in which different features can be fabricated. In contrast, AM needs only some basic dimensional details and a small amount of understanding as to how the AM machine works and the materials that are used. AM parts are made by adding material in layers; each layer is a thin cross-section of the part derived from the original CAD data. The thinner each layer is, the closer the final part will be to the original (Booysen, Van der Merwe & De Beer, 2019). There are a few significant benefits of AM: the automation of the production process, a higher degree of design freedom, and the resulting potential for optimisation (Knapp, 2017). It is, however, of utmost importance that the building components and the 3D printing processes be modelled correctly.

Figure 2.1: Example of different stages of AM

Figure 2.1 (Li, Fan & Zhu, 2020) indicates the different stages of AM, clearly showing that the product being manufactured consists of a various number of layers that are manufactured step-by-step (Dimov et al, 2001). Each layer follows on the previous, and thus the quality and exact conformance to specification for each layer are vital (Gibson et al, 2011). If one layer is not up to standard, the whole part will not be manufactured to specification and the part will have to be reworked or scratched completely.

2.1.4 **Medical implants and the AM process**

Following the initial purpose of simple model making, AM technology developed materials that comply with the 3Fs: Form, Fit, and Function. The concept of form helps to fully appreciate the shape and general purpose of a design. Improved accuracy means that components are capable of being built to exact required tolerances for assembly purposes. In the end, improved material properties mean that parts can be properly handled and do the function required (Function). The 3Fs are of extreme importance when it comes to medical implants, of which CRPM currently specifically targets the facial bones. Excessive cancerous growths are most often the reasons why these bones need to be removed. Many patients are left with minimal facial structure after surgery, and additive manufactured products are currently being tested to address this issue.

Many prosthetics are made up of parts that fit a certain range of sizes in a standard population group (Booysen, Van der Merwe & De Beer, 2019). This means that precise and accurate fitting is often not possible, and the patient may experience some post-operative difficulties. These difficulties can often lead to other post-operative requirements, including rehabilitation or even in extreme cases, corrective surgery, thus adding cost to the entire treatment course. Customisation usually ensures a greater sense of comfort and performance; here the implant is based on actual patient data (Zastrow, 2020). Patient data is gathered by any medical specialist who is familiar with the procedure and who can determine whether the treatment will be beneficial. The more thorough the patient data is, the more precise the implant can be. Specialised software is used that allows the patient data to be manipulated and incorporated into the medical device. One key to the success of customised prosthetics is the ability to perform the design process quickly and flawlessly. The use of direct and digital manufacturing makes it easier for manufacturers and practitioners (Gibson, Rosen & Stucker, 2010), in the sense that better planning can be done beforehand.

The AM of medical implants enables the personalisation of each implant in response to the patient's specific needs. The personalisation of implants means that more time is spent on the planning, designing, and manufacturing of the implants. However, according to 3Dnatives (2020), a 3D printing website, the solutions created through AM are viewed as more appropriate than most traditional methods in terms of the design, together with reduced time and manufacturing costs (Choonara, 2016).

Generally, the AM process starts with a CAD file that is created for the problem that needs to be solved or the product that needs to be made to solve the problem. The CAD file is then converted to an STL file, which is the accepted format for the AM machine. The AM machine then manipulates the file to the correct size, position, and orientation for building. It is important to set the machine up before building, which includes adjusting certain parameters like layer thickness (Ory & Fraysse, 2018). The next step will be the build step; this step is largely automated and carried out without supervision. Once the build step is completed, the part is removed. Some parts require post-processing to ensure that it is as strong as required and is acceptable for the required function. Finally, after post-processing, the part is ready for its use. Figure 2.2 shows an example of a medical implant or model (Li, Fan & Zhu, 2020).

Figure 2.2: Example of a medical implant

AM consists of various steps and interconnected processes. When these steps or processes deviate, it affects every part of the AM process. Parameters that can be affected by any deviation from the standard include cost, range of materials, maintenance, speed, versatility, layer thickness, and accuracy. Different implants will require different shapes, sizes, time, and possibly resources and each combination of the above-mentioned will possibly require a different amount of worker allocation, among other factors.

The medical industry has been an important factor driving innovation in AM. AM in turn remains valuable in this industry because of the time it saves when product development takes place (Kramer & Alami, 2016). Speed, cost, accuracy, material availability, and ease of use are all key issues that contribute to the reasons in favour of using AM. Certain factors must be addressed by the industry to ensure the correct use of AM: approvals, insurance, engineering training, location and technology. Each of these factors affects the use of AM in a way, such as: if the correct approvals for manufacturing are not obtained, printing will not be allowed, and the implants will not be allowed to be manufactured and distributed legally. Medical implants and the manufacturing process linked to them is expensive, which means that most patients who need them, will never be able to afford them by themselves. Finding a way to optimise the process chain or time usage in the process chain could lead to a reduction in cost.

Engineering training is another important factor. As new technologies are being introduced, employees need to be trained and familiarised with how the new processes will work. The better and more advanced the training is, the less the chance of unnecessary errors in the workplace. Training also ensures that safety is enhanced. Technology is necessary for AM processes to work without errors. For example, a machine cannot be put into action without a design is available that it can follow and for a design to be created, a CAD program is needed, thus the need for technological advances and training.

2.1.5 Process chains and change management

The formation of process chains is essential for product development (Averkamp, 2021). The process chain directly influences the costs of the product along with the production time and other associated parameters (Oettel et al. 2016). It also defines which and how many resources are necessary to produce the product (Anderson, 2018). Process chains change as different products have to be manufactured. Thus, change continuously occurs and change management needs to be implemented with the process chain to ensure efficient adjustments. Change management starts when an opportunity for growth or a need for improvement is noticed, in other words, when a need for change is identified. Potential change and goals surrounding the outcome of this change need to be identified (Jones, Aguirre & Calderone, n.d,).

Defining why change is necessary and defining what needs improvement, facilitates the creation of a solid foundation for successful implementation. The next step will to be prepare for the change that is about to be implemented. Preparation for design starts by understanding how things operate in the current as-is business state and what needs to be done to cross the chasm into the future to-be desired state. Continuous feedback from business employees on whether change works needs to be gathered. To prepare a business for a change, it is important to understand the process chain and identify problem areas. When preparing to implement change, training may or may not be included. Training, however, will be necessary if it is expected of people to do something new or different or work on a new system. At other times it is just a knowledge transfer that is needed, for example, implementing a new accounting system.

The third step in the change management strategy is the actual design of the change. Here it is important to establish who will be doing what and when. This includes who will be held responsible for the implementation of the change, who the change will affect, and what needs to be done beforehand to ensure the successful implementation of change. It is important to identify how large the change will be, whether it will affect the whole process chain or only a certain part of the process chain.

The next step in the change management process is to execute the actual change that was planned, this can start with the training of employees for certain or new roles that they will have to be able to do. This also involves the implementation of any new technology or programs that will be used. The execution of change usually spans over some time and runs parallel to certain other steps. Implementation or execution is where the real work of change management is. Here it is important to plan for implementation and transition, to manage resistance, and to be prepared to coach managers for change (Lutters, 2018).

It is important to have a transition plan; most transition plans cover:

- Tasks that need to be performed before the change (business readiness): here the question will be if the business is ready to take on a project such as developing and implementing a digital twin.
- People transition and process-related changes, e.g., communication, role restructures.
- Updated policies and procedures.
- Alignment of other organisational elements to support the transition. In the case of digital twinning, this has to do with the IT Team and their willingness to adapt.

Finally, it is important to sustain and monitor the change that was implemented. Sustaining the momentum of the change is important; it requires the provision of resources and support required for the life of the project. Some elements can slow down or negatively impact the sustainability of the implementation's momentum, including the perfectionist way of thinking, lack of focus, and not learning from experience. If these elements or the occurrence of these elements can be reduced, the chance of having a more successful implementation increases. When change is successfully implemented, the ultimate indicator will be an improvement in the return on investment (ROI). Successful ROI indicates that more money was made or less money was spent, thus indicating that time was utilised more positively.

John Kotter, an expert in the field of leadership and change management, has a theory of why organisational change usually fails. His theory states that senior management usually commits one of the following errors:

- Failure to establish a sense of urgency about the need for change.
- Failure to create a powerful enough guiding coalition that is responsible for leading and managing the change process.
- Failure to establish a vision that guides the change process.
- Failure to effectively communicate the new vision.
- Failure to remove obstacles that impede the accomplishment of the new vision.
- Failure to anchor the changes in the organisation's culture. It takes years for long-term changes to become embedded within an organisation's culture.
- Failure to systematically plan for and create short-term wins. Short-term wins represent the achievement of important results or goals.
- Declare victory too soon. This derails the long-term changes in infrastructure that are frequently needed to achieve a vision.

2.2 Research methodology

The process chain of a business is the blueprint to a business. It shows how processes are supposed to flow and how the business systems or the business should operate overall. The process chain can be used to measure where the current process is as opposed to where it should be, and thus can be used for problem identification. The process chain can also act as a guide to help improve the business as, when it is studied, one can identify areas where improvements should or could occur. To understand the process chain, it should be broken up into sections and subsections.

To understand the process chain and the risks associated, the steps below will be followed:

1. Use SWOT analysis to help map the as-is state of the business, as well as to identify risks.
2. Study and adjust the cause-effect diagram of the business to identify risks.
3. Analyse and determine the as-is and required to-be states of the business.
4. Discuss the process chain with experts.
5. Identify a suggested bridge to reduce risks and go from as-is to to-be state.

2.3 Research and findings

The following section expands on the literature that was found and elaborates on the steps mentioned under section 2.2.

2.3.1 Engineering research tools

Business analysis tools are useful techniques and tools that can help one understand the organizational environment and think more strategically about the business. Strategic planning is the process of developing the strategy or direction and plan of action to achieve the goals of an organisation. Key elements of strategic planning include developing a clear understanding of a vision, mission, or values as well as a current state assessment of the most salient internal and external factors to be able to make the best strategic assessments. Currently, there are Process Mapping Tools as well as Process Improvement Tools. Process Mapping Tools are used to map processes to gain a better understanding of how the process works - this is the goal of the objective, to identify how the process works and its problem areas.
Process Mapping Tools and when they should be used:

1. SIPOC (Suppliers, Inputs, Processes, Outputs, and Customers) Diagrams – Used when mapping out straightforward processes that don’t include conditions. Great technique if the company doesn’t want to implement any kind of software.

2. BPMN Process Flowchart – This technique is ideal for processes that can follow different conditional paths.
3. Swim lane Diagram – Similar to BPMN Process Charts however they show roles and responsibilities of different departments/stakeholders.
4. Process Chain Diagram – Maps out each step of the process and is detailed.
5. SWOT analysis – Similar to BPMN, however, it can be used to assess places, competitors, and businesses without prior knowledge.

Process Analysis Tools helps one get to the root cause of any inefficiency within the processes. Below is a list of Process Analysis Tools and when they should be used:

1. Fishbone/Ishikawa Diagrams – Used to pinpoint the different aspects of the process that need improvement, one can then identify which improvement method needs to be directed to which component of the workflow.
2. 5 Whys Analysis – Used when identifying the root cause of an issue.
3. Force Field analysis- Looks at the factors that help and hinder a process. This is great for deciding on which process improvements to implement.
4. Pareto Chart - Shows the impact of different inefficiencies. Helps one to prioritize process optimization so it is clear where process improvements need to be focussed on.
5. Workflow Analysis Software – Track how processes perform based on their KPI data.
6. As-Is vs. To-Be diagrams – Studying the current state helps organizations document, track and optimize processes for better performance, greater efficiency, and improved outcomes.

Improving the workflow is a process that requires a suite of different process improvement tools. Understanding how to map and analyse processes will help one to work out how to improve workflows. When it comes to improving processes, the benefits of business process automation software can't be understated. It helps to speed up workflows, cut back processing costs and reduce errors. Both process mapping and process analysis tools need to be used in conjunction with one another to achieve improvements in a business. As shown above there are various process mapping and analysis tools available and those mentioned are only a few among many. In section 2.3.2 the researcher will use some of the tools explained above to map and analyse the process chain at CRPM.

2.3.2 **Analyse the process chain using SWOT analysis.**

SWOT is a strategic analytical tool for assessing the strengths and weaknesses of a business, analysing opportunities available to the business, as well as threats faced by the business. With

SWOT analysis on hand, senior-level management can build upon strengths and opportunities and threats can be minimized. Accordingly, SWOT analysis can be a powerful aid for senior management to develop an appropriate strategy for business. SWOT analysis is aimed at businesses that want to improve their operational efficiency. SWOT analysis is beneficial if conducted with a specific objective or question in mind, for example:

- Take advantage of a new business opportunity
- Respond to new trends
- Implement new technology

When considering the three bullet points above concerning digital twinning at CRPM the researcher can confirm that the research wants to take advantage of a new business opportunity (involving digital twinning in CRPM), respond to new trends (the trend of digital twinning), and implement new technology (digital twinning technology) and because of this, a SWOT analysis was decided upon as a Process Mapping tool to conduct further research. The SWOT analysis helps the researcher to understand more about the process chain at CRPM and where the possible gaps are.

The process chain at CRPM consists of six main parts, each containing sub-steps. The six steps are sales process, implant design, the AM of prostheses, preliminary inspection, final quality checks, and dispatch. To understand the process chain and see what the as-is state is, a SWOT analysis is conducted. Opportunities and threats are external to the business and cannot be controlled. Strengths and weaknesses, on the other hand, are internal to the company; they can be changed over time, but not without some work. The SWOT analysis helps to map out the possible risks in the company.

Figure 2.3 below shows the SWOT analysis that was done at CRPM. It is evident that the business has many strengths and that these strengths should be used to implement strategies to lower the weakness column and to make use of the available opportunities. Certain risks have however also come to light and should be taken note of. To further the investigation into the process chain, SWOT analysis strategies were investigated to come up with possible solutions, as shown in Table 2.1 below. The SWOT analysis helps to identify the as-is state of the business by identifying current strengths as well as weaknesses. The SWOT analysis is also used to strengthen the as-is vs. to-be states that were mapped out in Table 2.1 by bringing possible areas in need of improvement to the front. The SWOT analysis aids in planning for the to-be state as now one can start brainstorming ways to prevent the threats from realising.

From Figure 2.3 and Table 2.1 a few risks can be identified at CRPM, namely:

- A trade-off needs to be found between time optimization, quality, and cost to ensure that limited time and money is used efficiently and effectively to produce the highest volume of products at the desired quality in the available number of hours.
- Research needs to be continuously done into the technologies that are available and into possible improvements that can be made to technologies to ensure that CRPM stays at the top of their game.
- Currently, sourcing raw materials is a big risk factor – if there are not enough raw materials, nothing can move forward in the process. Research should be done into finding the best way to source raw materials.

It is important to accept risk, but plan for it. That is the key: planning for change and possible risks that may arise.

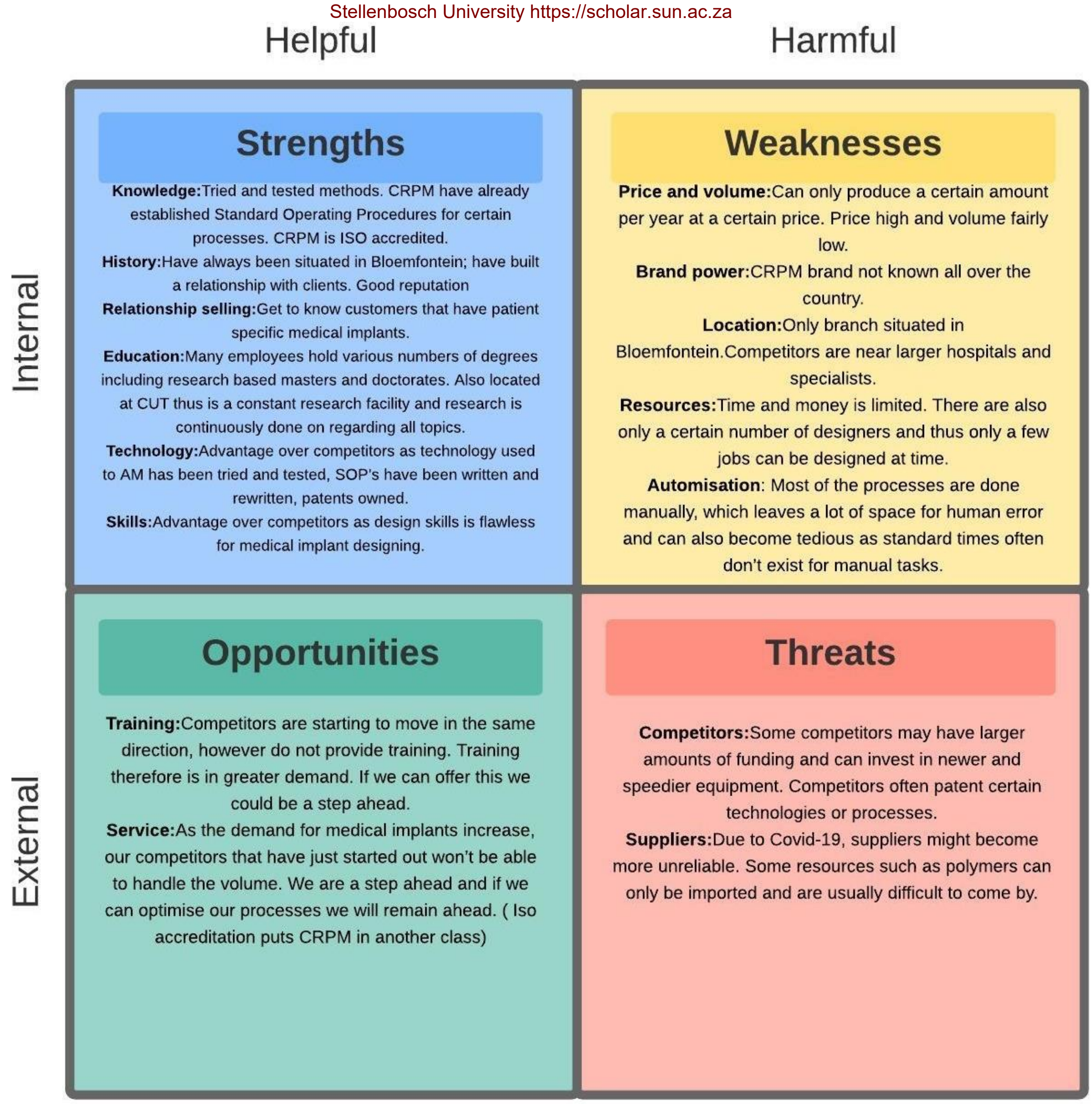


Figure 2.3: SWOT analysis

In Appendix B, the process chain of CRPM is depicted and can now be used in conjunction with the SWOT analysis to develop an As-Is vs. To-Be table, which is one of the Process Analysis Tools chosen. The process chain is another Process Mapping tool that was chosen as it shows the flow of processes in detail and provides a complete overview of the process. The As-Is vs. To-Be table was chosen as the research seeks to optimize time and ensure greater efficiency within the process chain which will lead to improved outcomes. The steps of the current as-is process chain are set out in Table 2.2 below, as well as what occurs in each section. The to-be column shows what the desired state of the process chain is and a bridge between the As-Is vs. To-Be states is suggested. It is necessary to understand each step, in detail, to obtain a thorough understanding of how everything works, where possible problems can occur, why these problems occur, and what can be done to prevent them from reoccurring in the future.

Risks that were identified in the As-Is vs. To-Be states in Table 2.2 below include time wastage that occurs in the process and the lack of time and money optimization. A possible bridge to this gap would be to do proper pre-planning and continuously update plans as the process progresses which in turn ensures processes run smoothly and as scheduled whilst remaining in budget and reaching the desired quality. Another risk identified is human error; some processes or steps in processes are done manually, automating these steps could reduce time spent on steps as well as possible errors or other risks associated with loss of data. A bridge was suggested, which could help CRPM go from the current as-is to the desired to-be state; in many cases the bridge suggested included a planning tool of some sort, the proper training of employees, and continuous updates to the schedule.

Table 2.1: SWOT analysis strategies

	Opportunities (external, positive)	**Threats (external, negative)**
Strengths (internal, positive)	**Strengths-Opportunities strategies** *Which of the business's strengths can be used to maximise the opportunities identified?* The knowledge, skills, and education that the business has, can be used to develop a training program for up-and-coming businesses or students who are interested in the area. In this way, the research area is broadened. All the business strengths that were mentioned can be incorporated to technologically advance the business. This means that methods can be developed where a higher volume of customers can be serviced at a time. Optimisation of the processes should lead to the optimised use of the business's time and resources. Planning tools, digital twins, improved ERP systems are all tools that could be used.	**Strengths-Threats strategies** *How can the company's strengths be used to minimise the threats that were identified?* Research can be done into ways to optimise the business for higher production volumes and more time optimisation. To optimise the use of time and money and to see the effect of automation, different scenarios need to be run and compared to one another. All strengths can be used to develop a digital twin which can be used to test the effects. If time and money are optimised, the business will run more efficiently than competitors. Having a digital twin in place will act as a planning tool that can help provide solutions when suppliers become unreliable; ensuring the business still reaches its goals.
Weaknesses (internal, negative)	**Weaknesses-Opportunities strategies** *What action(s) can be taken to minimise the company's weaknesses, using the opportunities that were identified?*	**Weaknesses-Threats strategies** *How can the company's weaknesses be minimised to avoid the threats identified?*

	By providing a training course or providing training for employees who work with AM, the business can create an extra branch of income.	Social media, which falls under technology, can be used as a marketing strategy to ensure that CRPM gets more brand exposure. More brand exposure means more customers, which means more money. Using digital twinning to make the company more automatic, will help with planning and less reliance on late suppliers.

Table 2.2: As-is vs. to-be states at CRPM		
Step:	**As-is state:**	**To-be state:**
Sales process:	The sales process is the first step in the process chain. Here, new customers are added to the system and a unique ID is created for each customer. The customer undergoes CT/MRI scans to see the extent of the issue that they are facing. The CT/MRI scans are used by the design team to start developing a plan of action and also identify the risks involved. The CT/MRI data is converted to STL format and can now be designed or edited using CAD. The STL format also indicates how much of which resource should be used and thus costs are estimated for the project. A quote and indemnity form will be sent to the customer, and it will either be approved, and the order will be placed or discarded. CRPM updates their order book and can now complete a job card.	The most evident factor picked up from the sales process is that most of the process is done manually. If the process can be done automatically, a number of the sub-processes or steps can be eliminated. As the sales step is the first step, it is important that the information received and cost estimation that is done are accurate to ensure a flawless flow in the rest of the process chain. When done manually, the chance of a human error occurring increases, and valuable time and money that can be spent elsewhere is wasted. *Bridge:* Making use of a sales field app could be a possible solution to bridge the gap from the as-is to to-be states. Field apps are planning tools that keep all customer information, such as scans, costs, time spent on the customer, time until a customer order is due, etc., in one spot. Every time a new client is acquired, the information is added to the app, which updates all records. A task that previously would have taken hours or days, is now completed in minutes and the risk of losing client information is eliminated.
Implant design:	The first step of the implant design phase begins when a preoperative skull replica model is additively manufactured using nylon. Once the replica is completed, it will be sent to the surgeon for further adjustments. The surgeon uses wax to adjust and change the model to desired specifications; this process may take a few days or weeks. The adjusted model is sent back to CRPM, after which the wax mock-up will be reverse engineered into a CAD model. Checks are done to ensure that the mock-up fits specifications. Once	The time taken for the surgeon to redesign the preoperative model with wax is the limiting factor here. Ideally, the model would be completed and returned to CRPM after a few days. This process is however seen as being outsourced, which currently places it out of CRPM's control. Here, the focus will remain on ensuring that all the processes surrounding the reverse engineering are flowing optimally and on time. The desired to-be state will be to plan all jobs in such a way that no time goes to waste. While the model

	the specifications are confirmed, the model will either be signed off or discarded. If the model is approved, the design of the prosthesis will be completed and supports will be added to the structure. The final step in implant design will be to position the parts on the printing platform, rescale and slice them. The implant is now ready to be manufactured.	is with the surgeon, the next preoperative model is designed and printed and the model received back is reverse-engineered and printed. *Bridge:* Have a planning tool in a place where CRPM can plan when to do what to ensure the optimal use of time. Train more than one designer so that not all pressure is on one person and time can be spent where it should be on each design. Ensure that plans are in place for when a surgeon takes longer than expected.
The AM of prostheses:	At the start of this step, the machine handler has to transfer the STL file to the machine. Sample parts are also added to the printing platform that will be used later for testing purposes. Now, a job file is created and saved, and machine availability is checked. Before starting the actual manufacturing process, the machine must be prepared. Prep-work takes a significant amount of time but is an important step that cannot be skipped. The machine is prepared by vacuuming all excess powder from previous jobs, spraying and wiping down the surfaces, and making sure that all parts are functioning as it should. The printing platform is inserted into the machine manually and the correct brush is added. The prosthesis is now ready to be built. Next, the actual manufacturing takes place, this may take from 1 hour up to a few days, depending on the size and complexity of the prosthesis. Once the job is completed, the prosthesis is removed, and excess powder is recycled.	The behind-the-scenes work at this step is as critical as the actual printing of the part. The sample parts will indicate whether the composition of the parts is correct and of the correct strength. The preparation of the machine is essential and should be done exactly as employees are taught – if the machine is not prepared correctly and old powder grains are left behind, it could cause an entire job to be disrupted or to stop completely. The quality of a job should not be compromised and the standard operating procedures that are set in place need to be adhered to. Plans should be in place if a print fails, or a machine was set up incorrectly and prints fail as a result. *Bridge*: Pre-planning is important to ensure that no time is wasted if something happens during a print (planning of resources/stock in hand). Proper training for the machine operator is essential.

Preliminary inspection:	Once the prosthesis has been removed, tests and treatments have to be done to ensure quality. Treatment is now done to ensure 12% ductility. Density tests are performed with Archimedes. A tensile test is done to determine if any faults occur within the structure. Destructive testing is also done (Micro CT scan).	Currently, there is only one machine available to do tensile tests. Ideally, adding another machine could speed up the process, but some prints take so long that by the time the next print is finished, the tensile test has been conducted. Ensuring that optimal pre-planning takes place to ensure that all parts are on time and of the correct quality, is important here. Ideally, no prints should be redone because of lack of quality. Plans should be in place if this is the case. *Bridge*: Planning for all types of situations, including a large enough lead time to ensure that if prints had to be redone, the schedule would not fall behind.
Final quality checks:	Once all tests and treatments have been done, final quality checks take place to ensure quality and conformance once again to specifications. Parts are now sent to an external company for cleaning of the prosthesis, packaging, and sterilisation. CRPM receives a report upon completion and the post-build job card is completed.	Some of the most important steps have been outsourced in this step (like sterilisation of products). However, if this process is not done correctly, it still reflects on CRPM. This outsourced process could cause a delay or bottleneck as CRPM has no control over how long the outsourced company will take per part. They should therefore allocate time for possible delays. *Bridge:* Ensure that the lead time is enough to account for final quality checks. Have outsourced companies continually give updates on the progress for CRPM to be able to update and schedule jobs accordingly.
Dispatch:	Finally, the product is packaged and labelled. The package is shipped to its end location, now the prosthesis is ready for implantation. CRPM completes an invoice, does a follow-up on how the surgery went, how the prosthesis fits, and records the information.	No changes are needed.

2.3.3 Cause-effect diagram

Another important Process Analysis Tool used is the cause-effect/Ishikawa diagram. It can be used to discover the root of the problem, uncover bottlenecks in processes and identify where and why a process is not working. It helps teams to understand that there are many causes to an effect. Cause-and-effect diagrams are visual tools used to logically organize possible causes to an effect and casually suggest relationships between theories. The Cause-and-effect diagrams give another view into possible problem areas in the process chain. Possible areas of improvement are identified, and it can be pinpointed which improvement method should be applied at which area. The tool was used to identify the largest risks in the process currently.

Step 1: Identify the problem

The three main risks at CRPM that were identified (Bezuidenhout, 2016) were quality, time, and cost. Three parameters walk together, but for this research, the focus will be on time as this is the most important factor as it is endeavoured to optimise the use of time at an AM business. Table 2.3 below shows the problems identified at CRPM in decreasing order of importance from Table 2.2 and the SWOT analysis.

Table 2.3: Three most important risks

Order number	Problem	Risk of problem
1	Time	The risk of not optimising the use of time and time delays during AM.
2	Cost	The risk of costs incurred during AM.
3	Quality	The risk of not delivering a certain standard of product.

Time is the limiting factor at CRPM and therefore needs attention. Only so many hours are available, and the AM machines work at a standard pace that cannot be changed. It is thus important to look at the time aspects which can be influenced, how important they are and how a possible change to these factors can affect the overall use of time. Time affects cost and vice versa: if the time taken increases, costs increase and vice versa. Finding a balance of how time and money can be used optimally is important for an AM business as manufacturing implants takes a long time and large amounts of money, thus making mistakes could hurt an AM business.

Figure 2.4 shows the current Ishikawa diagram which indicates the risk of time delays during the AM process of a medical implant. The main causes are distributed according to their importance, from left to right, and according to internal and external characteristics. Internal characteristics are above the fishbone and external are below. The secondary causes are distributed in descending order (Bezuidenhout, 2016). The full weighting calculations, as well as formulas, can be found in Appendix F.

From the Ishikawa diagram below, the critical path can be identified. The critical path consists of the causes that have the most significant effect on the time delays in the AM process. For this research, the focus will only be on the internal factors that are currently causing time delays. The table below lays out each main cause, associated secondary cause, their weights, possible risks, and possible solutions.

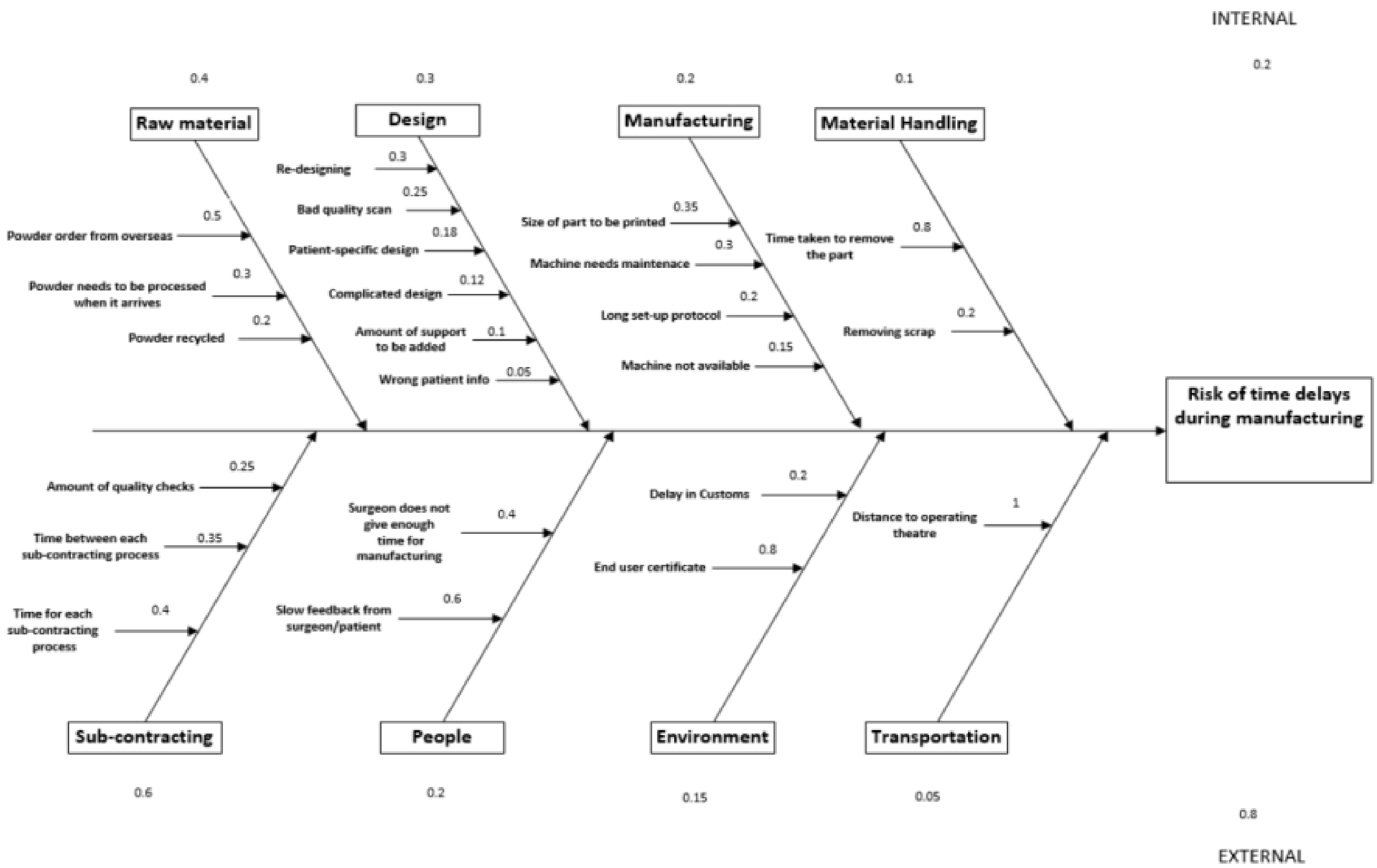


Figure 2.4: Ishikawa diagram - risk of time delay (Bezuidenhout, 2016)

The secondary causes, highlighted in red (Table 2.4), are the causes that have the most significant effect on the main cause, according to the calculated weights. However, after careful consideration, several risks were identified, that do not necessarily have the biggest risks associated with them however have quite an effect on the time usage (this is the exception, not the rule). For example: for the main cause, “Manufacturing”, the secondary cause which has the highest weight is “Size of the part to be printed”. The time that it however takes for a part to be printed, is fixed according to its size and level of complexity. In other words, the time taken cannot be changed by the business. For the cause of “Manufacturing”, the focus has to be shifted to the secondary cause that can be influenced to reduce risks.

Figure 2.5 below shows the Ishikawa diagram (Bezuidenhout, 2016) illustrating the risks of increasing costs incurred during manufacturing. All these costs are directly related to the processes which cause time delays shown in Figure 2.5. It can now be concluded that as the times for the processes shown in the table below increase, the costs shown in Figure 2.5 automatically increase as well. For example, if maintenance is left unattended, more maintenance would have to be done at once and possibly much bigger repairs that cost more money. In turn, the machine downtime would increase, meaning that less work can be done, and less income is received. The business should identify the risks and find ways to mitigate these risks or eliminate them.

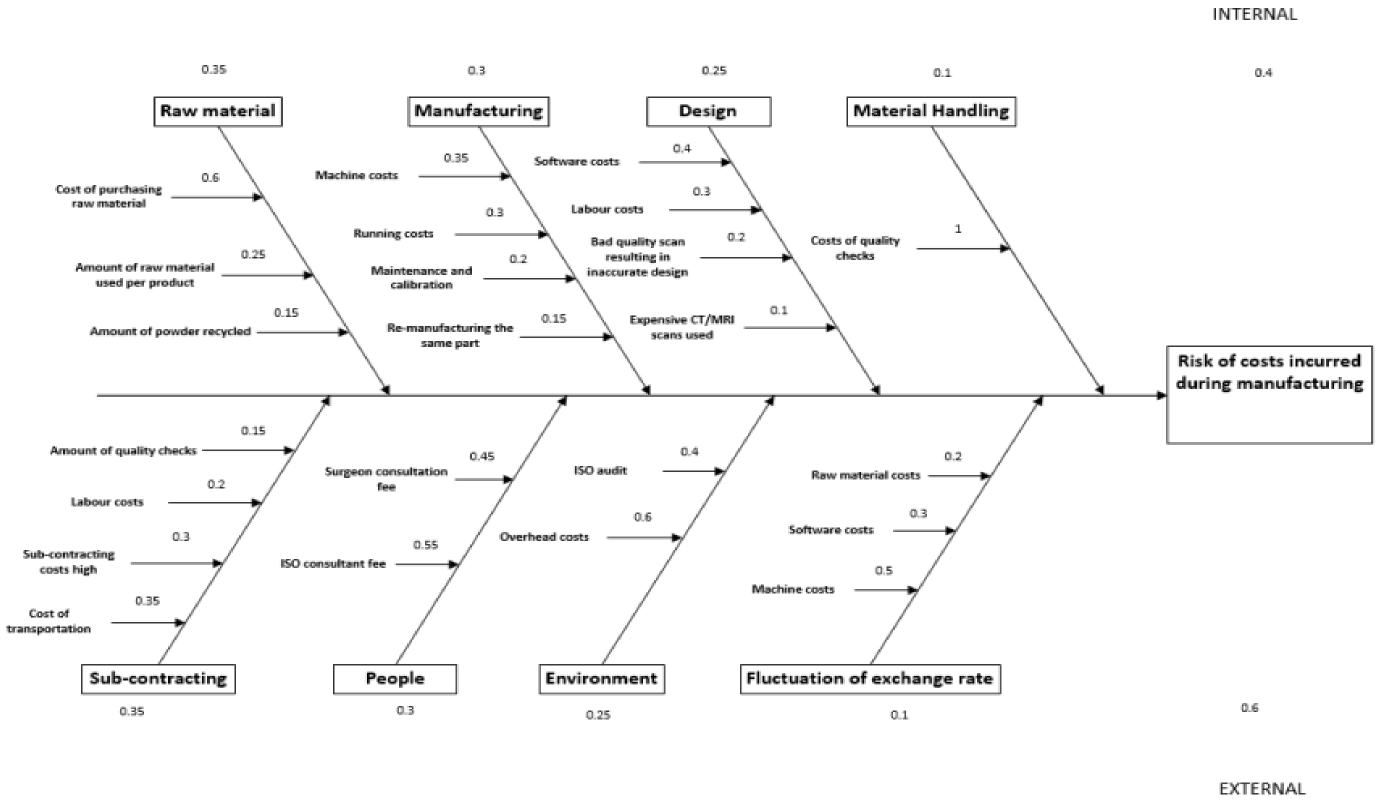


Figure 2.5: Ishikawa diagram - risk of time delay (Bezuidenhout, 2016)

Table 2.4 below shows which factors cause time delays, as well as the possible risks that arise.

A constant factor that is identified in the “Possible Solutions” column is the word “plan” or “planning”, which indicates that many of the risks identified could be mitigated by using a proper and sufficient planning system. This strengthens the argument that a planning tool could be a solution and should be investigated further. Table 2.4 also indicated that even if a secondary cause has the biggest weight associated with it, it does not necessarily mean that it can be improved. Highlighted in green in Table 2.4 are the secondary causes that can be improved to have the largest effect on the main cause.

Table 2.4: Risk identification using Ishikawa

Internal				
Main cause:	**Secondary cause:**	**Weight:**	**Possible risks:**	**Possible solutions:**
Raw material	Powder order from overseas	0.5	• If orders are delayed, not enough resources are available to carry on with work.	•Order powder in advance. •Ensure and plan to have emergency stock in hand.
	Process powder	0.3	•If powder is not up to standard, reorder.	•Emergency stock in hand.
	Recycle powder	0.2	•Unnecessary time wasted.	•Employee who works only on this.
Design	Redesigning	0.3	• Novice designers may take longer, make more errors, and have to redesign often. •Rate at which growth expands is not taken into account.	•Gather sufficient patient information for detailed planning. •Have plans in place for when redesign has to occur.
	Bad quality scan	0.25		
	Patient-specific design	0.18		
	Complicated design	0.12		
	Amount of support added	0.1		
	Wrong patient info	0.05	•Wrong print designed. •Wastes a lot of time.	•Double-check patient info.
Manufacturing	Size of the part to be printed	0.35	• Large parts take many hours; the machine is occupied for those hours.	•Ensure that supporting processes flow effortlessly. •Plan for long prints. •Avoid redesigns which may cause reprints.
	Machine maintenance	0.3	•If maintenance is not done often, machines may break down unexpectedly. •Unexpected breakdowns may lead to longer downtimes.	•Keep maintenance up to date. •Make provision for these downtimes.
	Set-up protocol	0.2	•If not done or done incorrectly, the part may be faulty or the machine may break down.	•Ensure SOPs are in place. •Factor in this time in planning.
	Machine availability (not available)	0.15	•Getting behind with jobs. •Redesign may occur if machines are unavailable for	•Ensure that supporting processes flow flawlessly. •Schedule other work during

			too long.	this time.
Material handling	Time is taken to remove part	0.8	•If not done properly, the part may be damaged. •If it takes too long, other processes are delayed.	•Make sure that SOP's (plans) are in place so that workers are never unsure of what to do next.
	Removing scrap	0.2		

2.3.4 Discussion of the risks

To verify the risks that were identified using the As-Is vs. To-Be analysis, SWOT analysis, and Cause-and-effect diagrams, several experts were interviewed, the full transcripts of these interviews can be found in Appendix A. From the experts' interviews, a general sense could be identified regarding certain factors in the AM process.

The most important factor between time, quality, and cost?

Expert opinion: To be competitive as an AM service provider, a balance should exist between production times, part cost, and part quality. There is no use in having a fast process resulting in poor quality or having a really good quality component that does not meet the client's deadline. However, it depends heavily on the application industry. AM lends itself well towards high-value, low-volume industries, the cost of AM parts is driven by the cost of the machines, as the machine cost drives the hourly rate of the machine. Accordingly, to manufacture parts at a lower cost, you need to focus on speed (time).

The biggest problem you have experienced in the AM business?

Expert opinion: High equipment and material prices due to Forex fluctuations, as well as a delay in getting material or spares from OEMs (Original Equipment Manufacturers) on short notice. Another problem associated with OEMs is the language barrier: when problems occur, they need to be addressed in their language as their first language is not English, which makes it a tedious process. They also tend to limit their machines to processes and materials that only they can work with. This means that if they are not working, the AM business cannot work. The OEMs need to provide the AM business with the materials and knowledge that they need, and time becomes a problem.

If you could alter one thing about the AM process, what would it be (big or small) and why?

Expert opinion: Increase manufacturing speed (more time available to do more jobs). Improved surface quality to reduce post-processing (saving time and money). Both these improvements walk hand-in-hand with broadening the research allowed to take place on the actual manufacturing of machines. Many technologies or machines used in AM have patents and thus the technology stagnates. The collaboration of ideas, research, and improvements could allow the manufacturing industry to grow and improve at a faster rate. Innovation should take place across all AM companies and not only a certain few, to allow the technology to get further along.

The biggest risk you have identified in the following AM processes: sourcing of raw materials and raw materials used in general?

Expert opinion: Safety risk in the handling and storage of reactive metals (titanium and aluminum).

In a South African context: we cannot manufacture raw materials on our own. Thus, materials need to be imported. This whole process becomes quite expensive and AM is therefore not a cheap venture in SA, so either a large lead time has to be planned to ensure that the company can wait for resources, or the company has to make prior provisions for enough resources. The sourcing of these polymers is generally also a difficult and expensive process.

Design process (medical implants, any object to be printed)?

Expert opinion: The handling of large data files. STL file formats can be huge when handling complex geometries. This causes issues with simulation and prediction software. There are also high costs associated with certified software.

The manufacturing process (actual print, machine set-up, etc.)?

Expert opinion: Part distortion during the build process causes prints to stop or fail, after which they have to be redone. Process monitoring is necessary to ensure consistent part quality, which links to the risk of part distortion during print. In a South African context, factors have to be taken into account which other countries do not necessarily have, such as power outages or shortages, which may cause prints to stop midway, wasting time and money. Operators who oversee machine set-up need to be trained well and monitored. Standard operating procedures (SOPs) need to be in place and enforced (in some places this is a difficult task). If machine operators do not follow the correct procedure during set-up or need to be checked up regularly, time and valuable money are wasted as prints must be redone totally or partially and more than one person may have to do one person’s job.

Material handling (removing supports, etc.)?

Expert opinion: Possible damage occurs to small and intricate parts during support removal, due to excessive force used. Operators need to be focused on the task at hand and be knowledgeable about it.

Do you believe sufficient planning tools (e.g., pre-process planning tools, training, etc.) exist to assist the AM process?

Expert opinion: Various valuable tools are available but at a high cost to acquire for limited use and small-scale production. An ideal would be to have access to such software on a case-by-case basis, for example on a token system. There is a place for planning tools. It is important to be able to plan the order in which tasks will be completed, as well as the time necessary to complete the task. It is important to plan how the process will flow, determining the importance or most optimal scheduling. If a job fails, a plan of how and when rescheduling will take place or whether the entire job or only a part should be reprinted should be in place. Various existing planning tools cater only for normal engineering works and not for AM businesses specifically and may not be suited or worth it.

2.4 Results

This chapter aimed to give the reader a general understanding of an AM business's process chain, to better understand the problem under investigation. This was done by defining the processes and conducting various tests to expose risks and problems within the process chain. Process mapping tools in conjunction with process analysis tools were used to study the process at CRPM. The investigation in this chapter clearly shows that one of the major problems at CRPM is the inefficient use of time and money available. Time varies as the product varies and varies from process to process as well. The time variation in completing the tasks makes it difficult to set standards and predict how long the entire process chain will last. The more time is wasted or spent on certain areas of work, the more that certain task costs and the possibility of going over budget increases. The to-be goal was identified as to be able to have proper planning in place, which will aid in the optimisation of time at CRPM.

The question now remains: How can the gaps between the as-is and the to-be states of the business be bridged? Objective 2 will explore a possible answer to this question. The research resulting in Objective 1 shows that a planning tool could be the answer to time optimisation at CRPM.

To understand the process chain, it was necessary to break up each part of the chain into its sections and subsections, research the times and costs associated with it and identify where problem areas are. It was found that idle times when the machine is undergoing maintenance (scheduled or unscheduled) and unplanned situations result in a large amount of time and money wastage.

If time is not utilised effectively, backlogs or bottlenecks may occur, causing several problems. Problems resulting from backlogs or bottlenecks include the following:

- Projects not being completed and delivered to the customer on time, causing customer dissatisfaction and the loss of business.

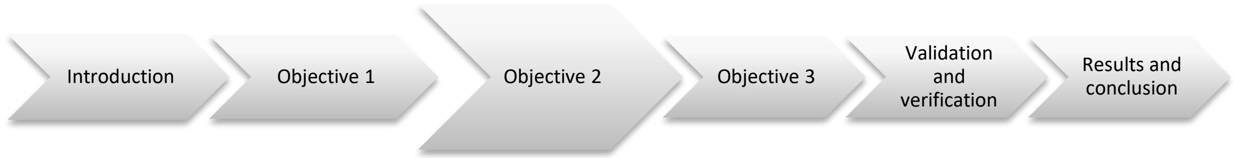
- Implants reaching the patient later than it was supposed to when growths might have spread so far that the original implant does not fit any longer and must be remade, which in turn wastes valuable time where other jobs could have been started.
- Other jobs that could have started, are delayed

The researcher has now identified a need for and areas of improvement. The requirements of the improvement are complex, and the process consists of various variables. The requirements for improvement align with the need to be able to do predictive maintenance as well as improve operational efficiency which includes using data to predict future activities. Before looking at the digital twin itself, it is important that the researcher thoroughly studies and investigates all the parts linking to it. The process chain acts as the initial blueprint for how the digital twin will operate.

2.5 Objective summary

Objective 1 gave the background knowledge that was needed to gain expertise on how operations work at CRPM. By studying the process chain thoroughly, it was possible to gain in-depth insight into where the major problems occurred and to start developing ideas on how to overcome these identified problems, keeping the idea of digital twins in the back of one's mind. Objective 1 was researched-based, and a few days were spent at CRPM working one-on-one with Mr. Johan Els to make sure that nothing in the process chain was misunderstood. Spending time at CRPM also gave the student a view of how day-to-day operations work and how everyday life scenarios change the way the processes work. This, in turn, helped that the research focus can be adjusted to not only work theoretically but can be applied to real-life situations. Four different research techniques were used to identify the risks at CRPM, namely: SWOT analysis, as-is vs. to-be analysis, Ishikawa diagrams, and finally, short interviews with experts. The research that was done in Objective 1 also confirmed the need for a bridge to fill the gap between the as-is and to-be states of the business. By using the information gathered throughout the objective, a suggestion to bridge this gap can now be investigated. The use of a digital twin will now be investigated further in Chapter 3.

3 CHAPTER 3 – OBJECTIVE 2: DEVELOP A DIGITAL TWIN TO INVESTIGATE THE BUSINESS PARAMETERS



This chapter describes the entire Objective 2, starting with the literature review through to the conclusions based on the findings. The objective is based on the research question. The literature attempts to answer the research question. Several articles and author reviews of Objective 2 – develop a digital twin to investigate the business parameters – will be outlined. In cases where there is a lack of literature, the researcher will focus on other ways of attempting to prove this objective. A methodology is then formed for this objective based on the literature review. Following the predetermined method, the findings are described, and several recommendations are made.

3.1 Literature

To be able to understand how a digital twin is developed, it is important to understand all aspects of a digital twin, i.e., not only the digital twin itself but also the building blocks that have to be used to develop it. Let us now look at the characteristics of digital twins.

3.1.1 Definition of the term "digital twinning"

A digital twin is a virtual representation of an object or system that spans its lifecycle, is updated from real-time data, and uses simulation, machine learning, and reasoning to help decision making (Armstrong, 2020).

Digital twins let us understand the present and predict the future. Not only do digital twins help us see how products/processes are performing but in combination with the data received from the process and among other things, one can analyse to see how it will perform. According to Wilkins (2020), marketing director of EU Automation, digital twinning is the mapping of a physical asset to a digital platform where it can be used for various purposes. The digital twin uses data from sensors located on the physical asset to analyse its efficiency, working conditions, and the real-time status. At its simplest, a digital twin is a virtual replica of a physical product, process, or system. The different categories that a digital twin can fall under are outlined below (Parks,2020).

- **Parts twinning:** This method uses virtual representations of the individual components to enable engineers to understand the physical, mechanical and electrical characteristics of a part. Computer-aided design/manufacturing (CAD/CAM) offers solutions and the capability to perform a variety of analysis relating to durability.
- **Product twinning:** Although the production of twins of individual parts offers useful insights, twinning the interoperability of parts as they work together helps to enable product twinning. Being able to understand how parts interact with each other and their environment allows for optimisation of the constituent parts, thereby maximising operating characteristics and minimising things such as mean time between failures and mean time to repair.
- **System twinning:** System twinning allows engineers to operate and maintain entire fleets of separate products that work together to achieve a result at a system level. Imagine using systems twinning across all types of system families. Groups that build and manage communication systems, traffic control systems, or industrial manufacturing systems will have an unheard-of ability to monitor and experiment with their systems to achieve unparalleled efficiency and effectiveness.
- **Process twinning:** Digital twinning is not just limited to physical objects; it can be used to twin processes and workflows as well. Process twinning enables the optimisation of operations involved in refining raw materials to produce finished goods. Purely business-focused workflows, even those that still have humans in the loop, would also benefit from DT modelling, as managers can now tweak inputs and see how outputs are affected without the risk of upending existing workflows, which would otherwise cause businesses to grind to a halt. Process twinning will enable management to monitor the most important business parameters in a much more data-driven manner than has been previously possible.

3.1.2 Digital twinning

A digital twin plays a transformative role not only in how we design and operate cyber-physical intelligent systems but also in how we advance the modularity of multi-disciplinary systems to tackle fundamental barriers not addressed by current, evolutionary modelling practices (IBM Internet of Things, 2017). Using data that is collected by digital twins, breakages can be predicted before they happen and reported to human operators to save money and time during production (Rasheed, San, & Kvamsdal, 2020). Businesses can order parts from companies that source automation components before faults occur, thereby reducing the risk of downtime caused by broken machinery. According to Jonathan Wilkins (2019), designers previously had little opportunity to test and amend their prototypes. Wilkins says that digital twinning models reduce development time and costs, as the final construction improves efficiency after analysing simulations. Digital twinning is more than just a blueprint; it is a schematic diagram or a pair of glasses that clearly shows how each step in the process works. It is a virtual representation of the dynamics of how an internet of things (IoT) device operates and lives its life cycle. A digital twin facilitates the actual operation of the product, starting at the design and continuing to the build and manufacture. Continuous learning facilitates the improvement of the manufacturing process. A digital twin needs to take into account possible tolerances, as it needs to be able to drift and shift as the product does. Constant recalibration of the process is necessary to see what happens and where changes occur, the analytics at every step is required to make decisions for the next step. Information regarded as important or that relates to changes in the process or product also needs to be recorded.

A digital twin acts as a living model that drives a business outcome. When designing a digital twin, it is important to determine the type of improvement that is required to be able to determine which modelling software is needed to create the 3D representation of the asset(s). IoT management needs to be secure as there will be different devices on a network and numerous risks involved. An identity driven IoT platform allows one to authenticate, configure, monitor, and manage each device on the network. It also helps to complete these processes quickly and securely. An identity driven IoT platform can manage the identity of every element involved in the digital twin and provide messaging services to automate secure communications between these people, systems, and things.

The more sophisticated the digital twin or its use must be, the more comprehensive the capabilities of data preparation, integration, and identification of management requirements will need to be. For example, most twins will look to exploit analytics to improve operational performance and decision-making. Controlling how data is ingested, stored, prepared, and presented is essential to enable one to apply advanced analytics. To achieve high-quality results, it is necessary to guarantee the quality of data coming from one's IoT devices. Each IoT device, including its rights to transfer and accept data, is verified. Taking an identity-by-design approach builds these capabilities into your digital twin from the outset. An identity driven IoT platform enables one to extend the capabilities of the digital twin quickly and securely through extensive integration and open APIs that allow new devices and applications to connect and interact with the twin (Ranger, 2020).

Digital twinning has many benefits. One of them is that new systems can be created and tested before manufacture. Companies can also test ideas for equipment addition and as well as possible service models before investing in building or implementation the physical change. If a model proves effective, its digital twin could theoretically be linked to the physical creation for real-time monitoring. The second benefit of digital twinning is that productivity and efficiency can be improved. In a 2017 prediction regarding the benefits of digital twins, Forbes suggested that it could improve the speed of critical processes by 30 percent. According to Gartner, industrial companies could see a 10 percent improvement ineffectiveness. A third benefit is that the widespread availability and diverse uses of digital twins give businesses in nearly all industries a better understanding of where processes can be streamlined and improved, thus helping to minimise downtime through the practice of predictive maintenance. Another benefit would be that digital twins allow for managing assets in real-time. Using digital twins to monitor daily operations and optimise and streamline manufacturing reduces unnecessary wear and tear on machinery. This then alerts business owners to potential money-saving changes, such as adjusting in fuel use. Faster maintenance and repair allow companies to maintain a competitive edge by improving overall output. The last benefit mentioned is that of understanding data to provide better service. Many digital twins have customer-facing applications, including remote troubleshooting. Using virtual models, technicians can conduct diagnostic testing from anywhere and walk consumers through the proper steps for repair instead of blindly relying on default protocols. Information gathered from these sessions provides valuable insights which could guide future product planning and development.

3.1.2.1 Digital twins in the industrial process

Physical characteristics have an effect on the feel, function, and look of the manufactured product. Thus, being able to monitor the physical stimuli such as temperature, pressure, vibration, and force is important to the product manufacturer. The use of digital twins for long-term asset management is relatively new but is likely to reduce the running costs of infrastructure and provide substantial savings over the operating life of built assets. According to Professor Tim Broyd, president of the Institution of Civil Engineers, the use of digital twins – and consequently the involvement of many more design, manufacturing, and asset management parties to collaborate at a much earlier stage than usual – has cut the cost of delivering capital-built assets by around 20 percent. Physical prototyping, according to the Business Times, will no longer be required with digital twinning, since this process will enable creating a product, process, or system, trying out every feature, testing every nuance, or ironing out every bug before it is built (Grieves & Vickers 2017).

Artificial intelligence (AI) and machine learning (ML) have had a great impact on the healthcare and AM sectors (Campbell et al., 2014). AI and ML technologies allow the user to be able to predict behaviours and trends or classify objects based on physical traits. With the aid of IoT infrastructure, a digital twin can be created. Developing a digital twin requires the combination of both physical properties and information communication technology (ICT) framework and software for data visualisation. Data visualisations represent real-world events and characteristics of physical objects and processes. To ensure that product quality meets customer requirements, specifications are developed. Initially, a physical prototype was built to collect and test data; however, this traditional method of using specifications is becoming outdated. As the functional needs and specifications of the physical prototype are updated, the actual physical prototype needs to be updated as well or must be rebuilt, which is a time-consuming and costly process. By using a digital twin, one can address the functional concerns through a visual representation of the physical prototype and save time and money in the process (Tereso, 2010). The digital twin acts as a virtual replica of the physical prototype. The correspondence between the virtual and physical objects is made through real-time data attainment from a functional unit. Data collection and monitoring of the physical prototype is done with sensors, which can be electronic or human, depending on what the digital twin needs to do. Sensors can be placed on the physical prototype or in the same room as the physical prototype to collect data. The sensor placement allows the digital twin to monitor and adjust its virtual behaviour in real-time, while an IoT software platform provides a connective interface between the physical prototype and the digital twin (Wilcher, 2019).

3.1.3 Time-driven activity-based costing

Standard times form the foundation for activity-based costing. With the historical records method, production standards are based on the records of similar jobs performed in the past.the Personal problems of employees may affect both their motivation to do a particular task and the speed with which they do it; therefore, the time that it takes to do specific jobs will also vary (Freivalds, 2014). It is important to allow for a time delay to mitigate the effects of employees' problems on the outcome of a particular job. Historical records have consistently deviated by as much as 50% on the same operation of the same job (Averkamp, 2021).

Standard times are calculated as follows:

Standard time (ST) = normal time (NT) + allowances (hours, minutes, seconds) (1)

ST = the time allocated to a task

NT = the time it will take a person to do a task under perfect conditions

Allowances = any ergonomic factors that might delay the execution of the task (e.g. extreme heat which leads to more breaks and a slower work pace, all leading to an increase in ST)

NT = observed time x rating (2)

Rating = an expert opinion of the percentage rate at which the observed worker performed their work during the observed time measurements

Observed time (OT) = statistical average time observed to do a task (Averkamp, 2021)

Employees require time to become proficient in any new or difficult operation. Frequently, time-study analysts establish a standard for a relatively new operation that does not allow sufficient volumes for the operator to reach top efficiency. If one uses the concept of output per operator (i.e. rating the operator out of 100) as a basis for operator grading, the resulting standard may be too high, and most operators will likely be unable to make any sufficient earnings. In contrast, if the analyst sets a standard for a new job that currently produces low volumes and the size of the order increases, problems may occur. Temporary standards eliminate this issue. The analyst establishes the standard by considering the difficulty of the work assignment and the number of pieces to be produced. Then, by using a learning curve for the work as well as the existing standard data, the analyst can develop an equitable temporary standard for work. The resulting standard will be considerably more liberal than if the job involved a large volume production. When released to the production floor, the standard is marked "temporary" and will include the maximum quantity for which it applies.

Work sampling is a technique used to investigate the time devoted to the various activities that constitute a job or work situation. The results of work sampling are sufficient for determining machine and personnel utilisation, allowances applicable to the job and production stations (Averkamp, 2021). The same information can be obtained when using the time-study method. However, work sampling provides the same information faster and at considerably less cost. In conducting work sampling studies, analysts make a comparatively large number of observations at random intervals. According to Freivalds, the ratio of observations of a given activity to the total observations approximates the percentage of time that the process is in that state of activity. For example, if 100 observations, taken at random intervals over a day, showed that the AM machine was working in 60 instances but was idle for different reasons in 40 instances, then the downtime of the machine is 40% of the working day. Optimisation of time is once again critical and thus time is the main driver. Once the concept of standard time is grasped, it is possible to apply the rand per hour concept to any process. This means that every hour that is used costs the business money; therefore, the less time is used, the less money is spent. Standard times are essential when using the time-driven activity-based costing method.

Time-driven activity-based costing (TDABC) is a cost-calculation methodology that estimates the costs of activities based on the unit cost of supplying capacity and the time required to perform the service in question (Additivemanufacturing.com, 2018). TDABC is a costing model that can handle the complexity and variability of daily activities and provide more accurate and transparent cost estimates. Kaplan and Anderson designed TDABC to simplify and reduce the cost of the implementation and maintenance processes of its forerunner, namely activity-based costing (ABC). TDABC simplifies the costing process since there is no need to interview and survey employees to allocate resource costs to activities. TDABC assigns resource costs directly to the cost objects using only two sets of estimates and both estimates are relatively simple to obtain. These two estimates are the capacity cost rate and customer service time. An explanation of how to determine these estimates follows below.

There are only two activities involved in a TDABC system. Firstly, the TDABC system calculates the cost of supplying resource capacity. For example, when a customer orders a product, the TDABC model calculates the cost of all the resources, personnel, equipment, and technology used in this process as well as any supervision necessary. After it has calculated these costs, it divides the total cost by the capacity, which is the time the employees have available to perform the work. This will give the capacity cost rate.

Capacity cost rate = cost of capacity supplied / practical capacity of resources supplied (3)

Secondly, the TDABC model uses the capacity cost rate to allocate departmental resource costs to cost objects by estimating the demand for resource capacity (usually time). The model requires only an estimate of the time required to process a particular customer order (Anderson, 2018). Each customer order time does not need to be the same and can vary. Because TDABC simulates the actual processes used to perform work throughout a business, it can capture far more variation and complexity than its forerunner, ABC, and it does not need a lot of data, people to process the data, or a lot of data storage space.

The TDABC model specifies the unit times needed for each instance of an activity. These unit times allow the business to see how much time is spent on a particular activity and how much time needs to be allocated to unused resources. The TDABC model mostly uses historical data, but its main strength lies in its ability to help predict the future. TDABC promotes the direct allocation of resource costs to cost centers using easily obtained estimations of two parameters for each group of resources, namely capacity cost rate and the time required to complete a transaction or activity (Anderson & Van der Merwe,2020). TDABC represents unused capacity more accurately as employee surveys tend to overestimate the time spent on activities (Bernhardt & Liu, 2007; Bezuidenhout, 2016).

Customer service time (min) = unit time x number of orders processed + unit time x number of customer inquiries + unit time x number of customer credit checks (4)

In 2015 a study was conducted on the use of a TDABC system on the clinical pathway for a total knee replacement (TKR) and to determine where the primary cost drivers lay (Additivemanufacturing.com, 2018). The study was done by applying the TDABC methods to a small cohort of TKR patients. About 20 patients were observed, and at each stage, personal, consumable, and indirect costs were calculated. Because mean times were not used, the results were more accurate than when using cost analysis or any basic top-down approach. The primary cost drivers were identified to be the cost of theatre consumables (including implant), corporate overheads, overall ward, and staffing costs for admission as well as for the operating theatre. The identification of the significant cost drivers makes it possible to better inform policymakers attempting to benchmark treatment costs. Possible discounts could include a reduction in length of stay for post-operative care, discount on implants and control of corporate overheads using elective orthopaedic treatment centres.

Gaining control of a business' is gaining control of the business. Idle times can add up to a large amount, and if idle times could be eliminated, more jobs could be fit into this time. TDABC is a new and exciting way to approach costing systems, and the saying that time is money becomes a motto for running a business.

3.1.4 Digital twinning and TDABC

To illustrate how digital twinning and TDABC can be related and work together for the benefit of whatever it is one is trying to achieve; a simple example will be used. Let's look at the process involved in baking cupcakes. Baking cupcakes is a simple process, some would say. Simply read and follow the recipe. The first step will be to read what ingredients are necessary and to make sure that the correct amount of each ingredient is available. If not, one needs go to the store to buy the ingredient; this is a step that could have been avoided if planning was done beforehand, thus time is being wasted. The unnecessary trip to the grocery store results in two problems, firstly, unnecessary money will be spent on petrol, parking fees etc., and, secondly, time that could have been used to start the process of baking cupcakes is lost to the trip. Time and money are lost. The next step when baking cupcakes will be to prepare the batter. To save time, one decides to switch on the oven so that it can pre-heat to the correct temperature. If this step was skipped, one would have had to wait for the oven to reach the correct temperature, thus wasting time. This step is another example that shows that if TDABC planning is done to minimise the amount of wasted time, certain activities can happen at the same time. The next step will be to pour the batter into the cupcake holders and place the mixture into the ovens. Then, while one waits for the cupcakes to be baked, a new batch of batter could be started or the kitchen could be cleaned, once again doing more than one thing at a time, utilising electricity, and again saving time and money. The digital twin will form part of the planning phase of the baking process. If one had used a digital twin, one would have known beforehand how much of each product would be needed, how much time is required, and which steps could be done when to reduce the time spent on the entire activity. One could possibly also have known what the optimal time was for baking the cupcakes. Thus, the digital twin is a tool used to improve the TDABC method.

Digital twins allow businesses to see what could possibly go wrong. In return, businesses can order necessary parts needed to fix the problems before they occur, thereby reducing the risk of downtime caused by broken machinery. Designers previously had little opportunity to test and amend their prototypes (Boschert & Rosen, 2016). The marketing director at EU Automation says that digital twinning models reduce development time and costs, as the final construction (followed by analysing simulations) improves efficiency (Boschert & Rosen, 2016). Going back to the cupcake example: the digital twin will show where possible problems may occur e.g., when the oven may cause problems and when the cupcakes will start to burn (i.e., temperature monitoring), and by knowing this beforehand, these problems could be prevented. Before the business gives the go-ahead on a project, planning must be done. If the planning is time-based and a digital twin is used, planning becomes even more flawless. Businesses will now know how much each step will cost based on the time that it will take. Possible flaws will be identified, and plans can be put into play to mitigate these flaws. As processes are optimised, waste is reduced, more time is available, more jobs can be done and income increases.

3.2 Methodology

There is more than one approach when creating a digital twin. It is important to know why one is developing a digital twin and for which intended use. Each parameter and strategy have its advantages and disadvantages. The goal of AM is to achieve a rapid fabrication time; therefore, parameters and strategies should be optimised for time. From Chapter 2 we identified that the main risks are time and money. Thus, we need to attempt to reduce the risk by investigating the possible use of a digital twin. The following steps were taken to initiate the development of a digital twin and investigate the business parameters:

1. Determine the steps needed to develop a digital twin in detail
2. Initiate the development of a digital twin
3. Explain and identify the complexity of using a digital twin

3.3 Research and findings

The following section expands on the literature that was found and elaborates on the steps mentioned under 3.2. This includes the steps needed to create a digital twin as well as the technologies needed.

3.3.1 Steps needed to create a digital twin

A digital twin is a system of building blocks where if all the building blocks are functioning correctly, then only will the digital twin function. However, each building block needs to be developed, trialled, and tested for its functionality simply before it can function successfully in the complex system of a digital twin. Digital twinning is commonly viewed as a form of disruptive technology, and not many people are familiar with the concept and find it daunting (Rossi, 2017). Research helps us to form a comprehensive idea of the topic, and it is a vital step in creating a digital twin. The more knowledge one has on the topic, the better the chances are that, if problems occur, it will not take long to find a solution. The idea of a digital twin is to create a digital version of a real process or service, and then run an analysis and prevent possible problems from occurring. Further, the digital twin allows the running of digital simulations, providing the chance to improve the process and prevent unscheduled downtime. Creating a digital twin seems like a daunting task, and thus it is important to tackle the project step-by-step.

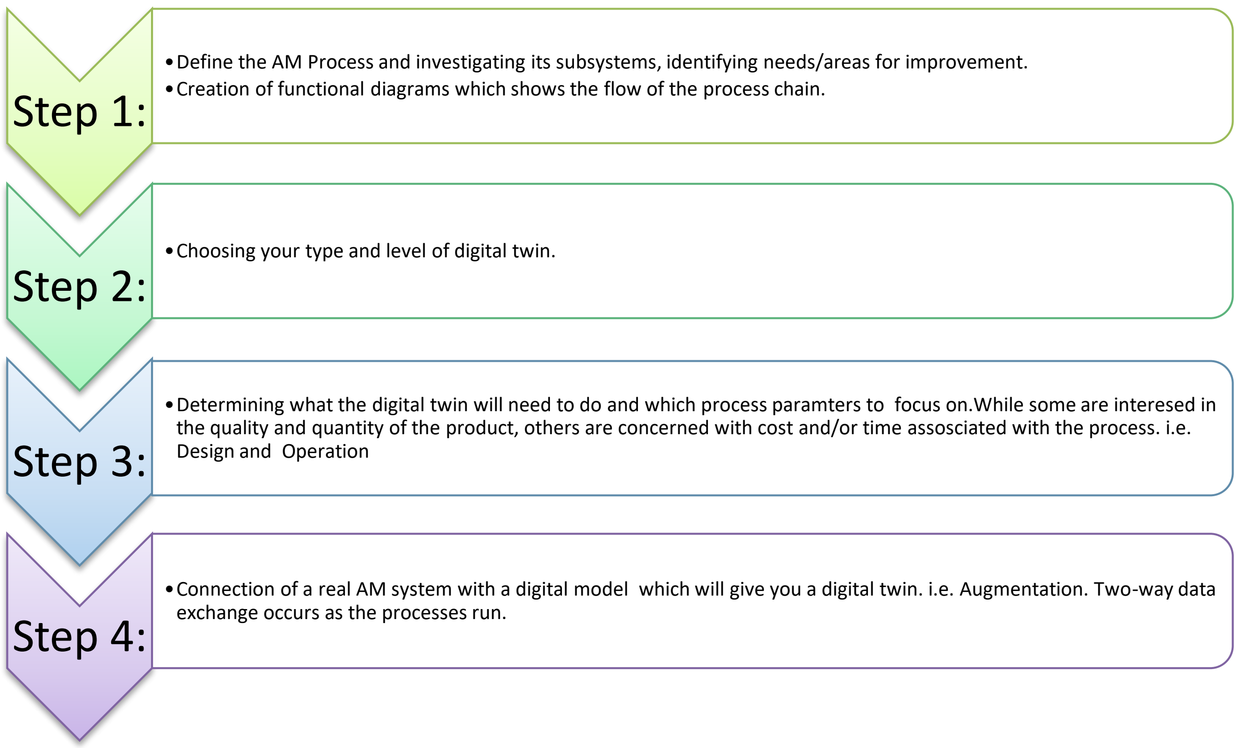


Figure 3.1: Steps to develop a digital twin

Figure 3.1 above shows the steps needed to create a digital twin. Step 1 was completed in Objective 1 where the process chain was investigated using various methods and areas in need of improvement were identified. A complete view of the process chain can be found in Appendix B. Steps 2-4 will be discussed in the remaining Objectives.

Step 2: Choosing the type and level of digital twin

Before commencing with the actual design of the digital twin, one needs to establish the type of digital twin that will be created. This will affect all the steps that follow as well as what each step entails. The four types as mentioned in the literature are product, process, system, and process twinning. As the research focuses on AM processes, we will focus on process twinning. If we can use a digital twin to optimise a process, we will be able to optimise time. There are currently three levels of digital twinning.

1. Level 1 - Basic level: Asset monitoring & control (manual)
2. Level 2 - Middle level: What-if simulations
3. Level 3 - Advanced level: AI-enabled systems

This Objective will focus on Level 1 and Level 2 type digital twins which act as the building blocks for Level 3 Digital Twins. Level 3 will be left for further studies as it is of a much more complex nature.

Step 3: Design and Operation

Design:

For this digital twin, the necessary technologies needed will include only AnyLogic. AnyLogic will be used to simulate certain processes, thus AnyLogic will act as a digital twin of the real process. From the literature, it was found that sensors can be humans or other devices. Sensors in this case will be the employees who take down times and the sensors will also record all relevant data. An objective of the digital twin is to make predictions and thus be able to change and adjust the times used in the processes. The simulation that is built on AnyLogic can be changed and adjusted as needed to see the effect of different situations on the process. Process capacity, Utilization of certain subsystems, Waiting time, Machine time, etc. will all need to be taken into account.

Operation:

Once the type, design of the digital twin, what it should do for the business, and the questions below have been answered, one will now determine what type of devices will need to be attached to the asset and whether it will be necessary to use more advanced devices. The answers given to the questions below also determine how the data will be prepared and integrated. Management requirements will also be determined.

- Should it monitor the asset?

  Yes, it should. Thus, it is a Level 1 Digital Twin

- Do you want the twin to control and alter the asset?

  No, resulting data will be used to make predictions and plans. The person using the digital twin will enter newly adjusted data manually. Thus, it is also a Level 2 Digital Twin as what –if conditions should be able to be run.

- Do you want to make data from the asset available for advanced analytics to assist with predictive maintenance?

  Yes.

Time needs to be available constantly, and management needs to be able to take the time, vary it and analyse the results. The digital twin constantly needs to keep up with the changes that occur, in this case, the person operating the digital twin will be responsible for making any updates or changes to the digital twin. Management wants to determine the standard times of the process and the sub-processes, where after they would want to determine where they are currently at and drive the process towards these standard times to ensure optimal process flow and production.

Step 4: Augmentation

The digital twin being developed in this research is only the foundation. Soon, and with more research, layers and technologies can be added to advance the operations and functions of the digital twin. It is important to start with a solid foundation and build the digital twin up from there. Starting small also helps employees to get used to the digital twin and how it works. In this way, the employee will be able to slowly learn more and more about the digital twin as it progresses and becomes more complicated. The AnyLogic examples that are used will act as an example to show what digital twins can do and how they can be used. It is a very simple example and is only used for explanation purposes. The physical process of the digital model is the AM process at CRPM and thus a physical version exists of the virtual replica. Data from the virtual replica can be used and implemented in the physical AM process and so a two-way data exchange exists.

3.3.2 **Technologies needed to build a digital twin**

For this research, the technologies needed are software that will allow the user to build replicas of process chains as well as costing systems. After doing research on the existing software and taking into consideration which software is available for free or at a low cost, the researcher decided that AnyLogic was the most suitable software. AnyLogic allows the user to simulate extensive process chains and costing systems and also allows the user to simulate the parameters that the user finds necessary to test. The software is also not too complex to use in the short time that most companies have available. The user only needs basic java coding knowledge, and multiple resources are available to assist in training. More complex models, such as the professional version of AnyLogic, can also be purchased by businesses.

3.3.3 Manual versus automatic digital twins

Digital twins are a popular topic with regards to Internet of Things. There are many different implementations of digital twin technology. A digital twin can be created automatically when a connection between the field and the cloud, using an edge device, exists. However, it is also possible to create a digital twin of the device differently. For example, scanning the serial number of an item, taking a picture, or adding the information manually to the cloud using a smartphone. Figure 3.2 below shows the necessary connections between the AM process and its digital twin. The most important factor here is that there should be a two-way transfer of data between the physical and virtual processes. Data is received from the physical process, entered into the digital twin (manually) the digital twin runs, the data is then fed back to the physical process and the cycle continues. The digital twin thus updates in real-time, as it updates as the physical process runs.

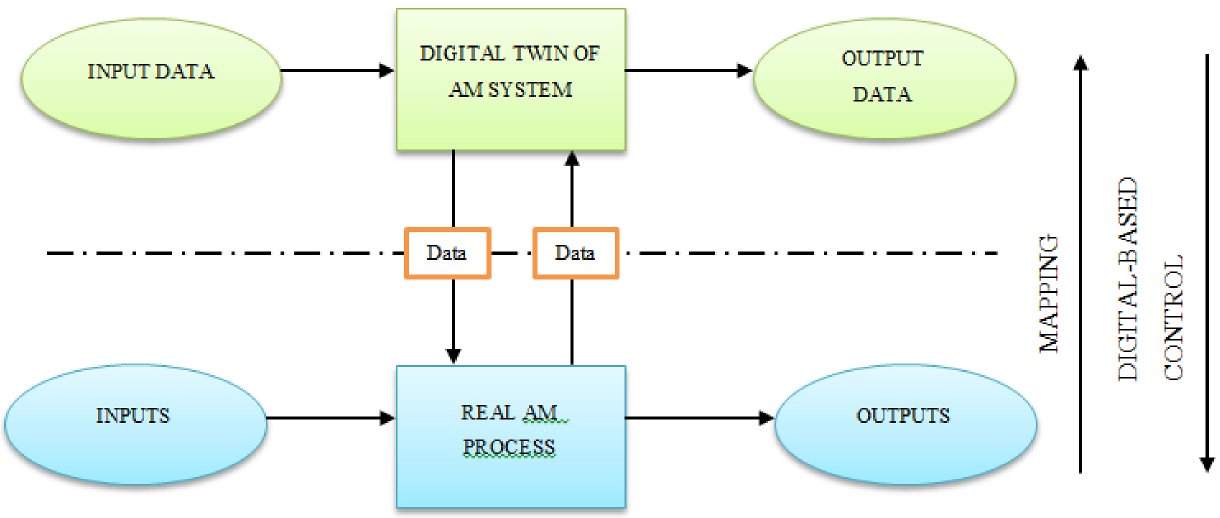


Figure 3.2: Data transfer between the digital twin and the physical process

In the case of the digital twin being investigated in this research, data was fed into the digital twin manually. Not all data was fed manually, only the parameters that are set to be editable to see the effect of the changes on the process. Other data updated automatically based on the previous rounds data.

Digital twin models can monitor physical objects, optimize their operations, and fully control their behaviour. Depending on the business goal, there can be three scenarios of digital twin use with different complexity levels (Sidyuk, 2021).

1. Basic level: asset monitoring to create a DT (digital twin), data engineers collect relevant data on the real-world object (real-time and historical sensor data, maintenance data, etc.). Subsequently, they feed that information to DT software (i.e., Anylogic – this can be done manually or automatically) that creates a virtual model of the object. Such models allow for monitoring physical assets and collecting data on them for future use. On this level, DTs are no more than data historians with intuitive interfaces, both in terms of functionality and costs.
2. Middle level: what-if simulations- Basic DT's can be augmented with what-if models. This enables companies to experiment with operational settings of assets or processes to find the optimal operational configuration. Here different parameters can be tested to see the effects on the process.
3. Advanced level: AI-enabled systems- DT's also can be equipped with machine learning (ML) algorithms that are trained on data collected by sensors. Such systems can quickly detect abnormal behaviour and suggest or initiate corrective action. These are fully functional and fully automatic digital twins.

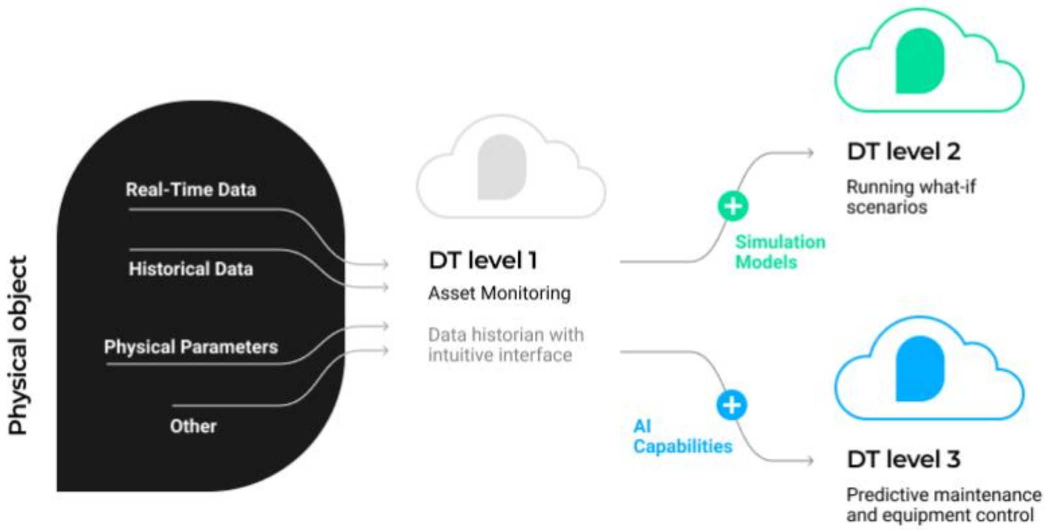


Figure 3.3: The three levels of digital twinning (Sidyuk, 2021)

Figure 3.3. above shows the three levels of digital twins explained. The digital twins that will be built and explained in the remainder of this research will be a mixture of level 1 and level 2 DTs. Level 1 as the DT will use historical data, real-time data, and physical parameters in combinations with simulations models to run what-if scenarios. Level 1 and 2 digital twins can still have some form of manual data entering and only once one reaches Level 3 is complete automation necessary. The Level 3 digital twin can be developed in further research or practice.

Digital twins are used in manufacturing to simulate the production process (in this case the additive manufacturing process). Based on data connected to machines, manufacturing tools, and other devices, manufacturers can create virtual representations of a real-world product, equipment elements, production process, or whole system. For maintenance purposes, digital twins allow for the monitoring of equipment health and recognizing potential anomalies in a timely way. DTs capture real-time data and together with historical data regarding failures and contextual maintenance data it allows companies to take proactive measures to prevent production stoppages. The above reiterates that digital twins are fed through data.
Digital twins are complex technologies however in the case of this research the information was entered manually. With further research and development, the digital twin can be made automatic.

3.3.4 CNC Machines compared to Additive Manufacturing Machines

A CNC machine processes a piece of material to meet specifications by following a coded programmed instruction and without a manual operator directly controlling the machining operation. The major difference between CNC and 3D printing machines is that CNC machines are subtractive and 3D printing is additive manufacturing. This means that CNC machines start with a piece/block of material, and it slowly cuts away at the material to make a specific object, however additive manufacturing creates an object layer by layer. Additive manufacturing uses energy such as those from a laser to form the object intended.

Both CNC Machines and Additive Manufacturing machines are used to manufacture something via a process. CNC via subtractive manufacturing and the other by additive manufacturing. Although the two machines differ, they are also similar in nature. As the Anylogic software currently does not have additive manufacturing machines embedded in the technology, CNC Machines were used as a placeholder to show what the researcher meant or to give a visual aid of how a digital twin for additive manufacturing will work. The research can be adjusted and developed further as per individual or business-specific requests.

3.4 Results

Two examples were simulated using the AnyLogic software. Anylogic is a powerful tool for creating and integrating a digital twin. This software was chosen as it can integrate many processes in one place and give the user a single view of all that is happening.

Reasons for using Anylogic:

1. Anylogic has proven application in a variety of industries and is comprehensive and customizable.
2. Multi method modelling - Combining agent-based, discrete event, and systems dynamics modelling for general-purpose simulation is a unique feature of AnyLogic used by world-leading companies and across industries.
3. Open API and programming ability -AnyLogic models are fully extensible at the code level, providing unlimited modelling capabilities. A model can be configured from an external data source when it is run, which means that the whole model structure can change by simply changing the input data. As a result, modellers have the freedom to choose and reuse the most appropriate methods for their projects, and simulations can also fully configure themselves using connected data.
4. AnyLogic Cloud – AnyLogic has a fully functional cloud platform that can be accessed via subscription or in-house (this is not available on the free version).
5. Ease of use - AnyLogic allows the use of visual modelling languages, scripting, and extensibility.

The student created a digital twin which falls in the process twinning category, meaning that it was used to mimic processes and workflows. As mentioned in the literature process, twinning assists the optimisation of operations involved in refining the use and production of raw materials and finished goods.

AnyLogic Learning version was used as it is what is available to the student. The full version of AnyLogic is not currently available to the student and thus certain features of AnyLogic were not available.

3.4.1 AnyLogic example 1: TDABC system

As one of the problems identified at CRPM was the control or optimal use of their money, it was important to simulate a costing system. A TDABC system was simulated.

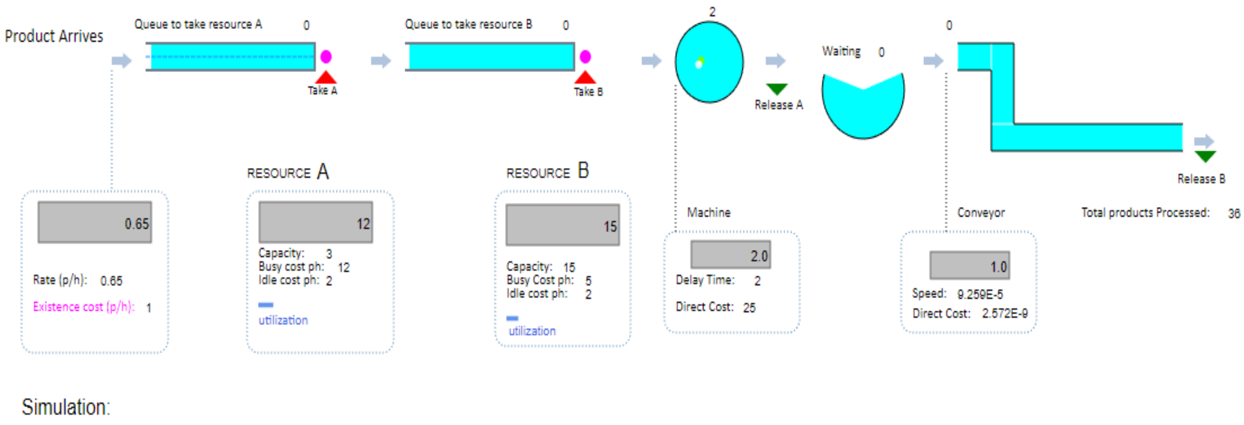


Figure 3.4: Animation of the TDABC system

Figure 3.4 depicts the animation of the TDABC system. This animation shows how the process works or flows, while the output which shows the results when the process is run is shown in Figure 3.5. The complete image can be found in Appendix D.

3.4.1.1 Applying the example to 3D printing of medical implants:

The process starts when a request to print/manufacture an implant is received. As an implant/product is now needed to be manufactured, the process is initiated.

Scenario 1:

The first thing that needs to happen when the request is received is the implant needs to be designed from the scans that were received. In this case, Resource A is the design phase, here the Capacity will be the number of people that are available or have the knowledge to design, thus the number of implants that can be designed at a time. The busy cost p/h is the time it takes to design the implant. The idle cost p/h would be how long the design phase must be because of various reasons. Once the design phase is completed the design will be taken and applied to the next phase. Resource B acts as the next phase, this phase is where the design is used to print pre-operative models which are sent to the surgeon for him/her to inspect and make changes before final printing takes place. In this case, the Capacity is the number of prints that can be at the surgeon at a time. Once the preoperative model is received the final changes can be made to the design now it is ready for the final manufacturing. The next step is the Machine step, here the actual implant will be manufactured, the Delay time would be the time that is lost because of unscheduled maintenance or that the print has to wait as the machine is busy. The direct cost would be the total amount it costs for printing the implant i.e., for the powder, the electricity, the labour etc. Once the implant is completed it will be released/ taken out of the machine. The next step is the waiting step, here the implant is treated (this is usually outsourced and so out of the company's control). The final step will occur once the treated implant is received, this is the conveyor step. The conveyor step is the phase where the implant is transported or sent to the customer. The speed is how long it takes to be delivered and the direct cost is the cost of transporting the implant.

Scenario 2:

This second scenario is more of a magnified look at the actual manufacturing process. The process is initiated once the preoperative model which was adjusted by the surgeon is received. Resource A acts as the Design-Adjustment phase. Here the design is adjusted and altered to fit the exact specifications as required by the surgeon. The Capacity is once again the number of employees that can work on designs. The busy cost p/h is how much it costs to work on the design per hour; the idle cost per hour is how much it costs to have the design wait. The next step will be that the machine needs to be prepared and set up for the manufacturing to begin. Thus, Resource B is the preparation phase, where an employee will load the design into the machine and prepare the machine (e.g., clean the machine, insert the printing plate, insert the correct powder). The busy cost is how much it costs per hour to prepare the machine, the idle cost per hour is how much it costs for the machine to be unoccupied while the preparation occurs. The next step is the Machine step, here the implant is manufactured. The direct cost is how much it costs to print the implant; the delay time is the time that nothing is being manufactured. The next step is the waiting period, this is the time while the machine is busy printing the implant, here nothing else can be done but waiting as the machine cannot be sped up or prepped for the next job until it is finished. The final step will be where the manufacturing of the implant is completed and now it will be removed, and the support structures will be removed.

The two different scenarios explained above are an indication of how customisable and adaptable the model is showing that it can be changed to fit the process that the company is currently busy with. The model also has the potential to be developed further to become more sophisticated and accurate.

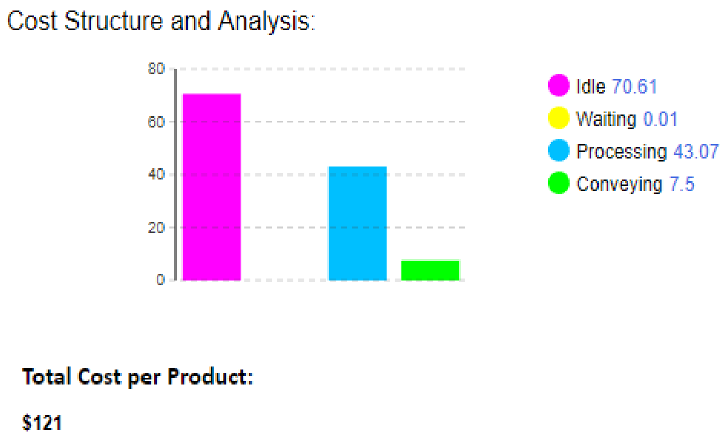


Figure 3.5: Cost Structure

Figure 3.5 is an indication of how much of the total time is spent in what area. In the case of Figure 3.5, the most time is spent in the idle process meaning that there is a lot of time where nothing is occurring, the least time is spent waiting, the second-highest time is spent in processing. The actual machine print time can not be adjusted as it is a fixed time, however, the idle time, waiting time, and conveying time can be adjusted to ensure that the process is more optimized. Figure 3.5 also shows the Total Cost Per product. This figure will change as data in the process is altered.

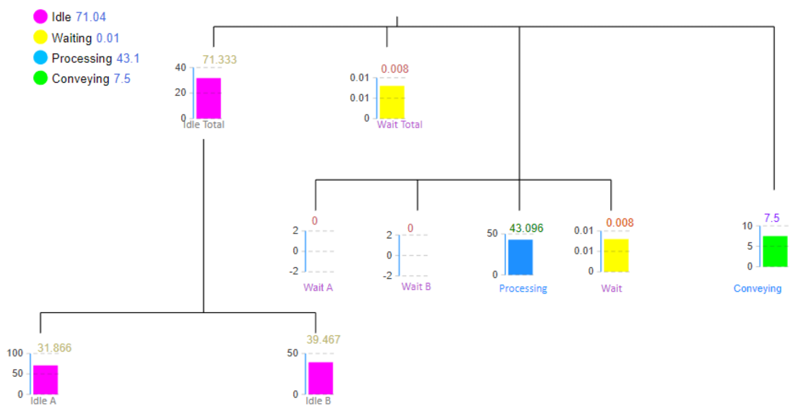


Figure 3.6 Second part of cost structure

The second part of the cost structure shown in Figure 3.6 shows many bar graphs, namely Idle Total (which is split into Idle A and Idle B), Wait Total (which is split into Wait A and Wait B), Processing and Conveying. This helps the user to see where exactly the time is spent and what resources are using it. This type of analysis of the costing system is beneficial as the company or user sees which operation in the process chain is taking up the most time and possibly the most money as well. Each time the simulation is run, Figure 3.5 and Figure 3.6 update for every product that enters the system.

3.4.1.2 The simulation and SOP's

Standard operating procedures (SOP) are a set of step-by-step instructions compiled by an organization to help workers carry out routine operations. Concerning the additive manufacturing process of medical implants, a SOP that is in place is the preparation of the machine before the implant is printed. Here the same steps are followed every time the steps are namely:

- Put on protective clothing
- Ensure the machine is switched OFF
- Open the machine
- Use a special vacuum to suck up all leftover powder from the previous print and to clean the machine – this is a very important step as the implant could be faulty if powder is in the machine when the new print is started
- Place the printing platform inside the machine
- Load the powder for the print
- Close the machine
- Load the design onto the machine
- Start the machine

In Scenario 2 this SOP was taken into consideration.

It is important to note that the following was not taken into account:

- Human error
- Idle time due to preparation of resources
- Downtime because of maintenance

Thus, the process was conducted in ideal conditions. Should the digital twin be developed further, and the level of complexity increased, SOP's can be added as the development occurs.

3.4.1.3 How are the AnyLogic examples beneficial?

Each time the process runs, results are obtained; these results can then be used to decide to adjust certain variables. The process can then be run again with the changed variables and once again results will be obtained. Now one can compare the results from the 1st and 2nd processes and decide based on these results. In the same way, decisions can be made for the next process to be run. In this way, the process can make improvements, adjust, and adapt each time. This is the same for a fully functional digital twin. Digital twins adapt and adjust as the process learns more about itself. The process can be repeated as the system grows and is developed to continually improve the outcomes.

The process can be altered to meet certain time expectations i.e., optimise the use of time or optimise the use of money. By using the digital twin method, the process is altered and changed until an optimal outcome is found. Using the digital twin provides solutions for the physical process without making any physical changes and so solutions to physical problems can be obtained without spending money on altering the actual process.

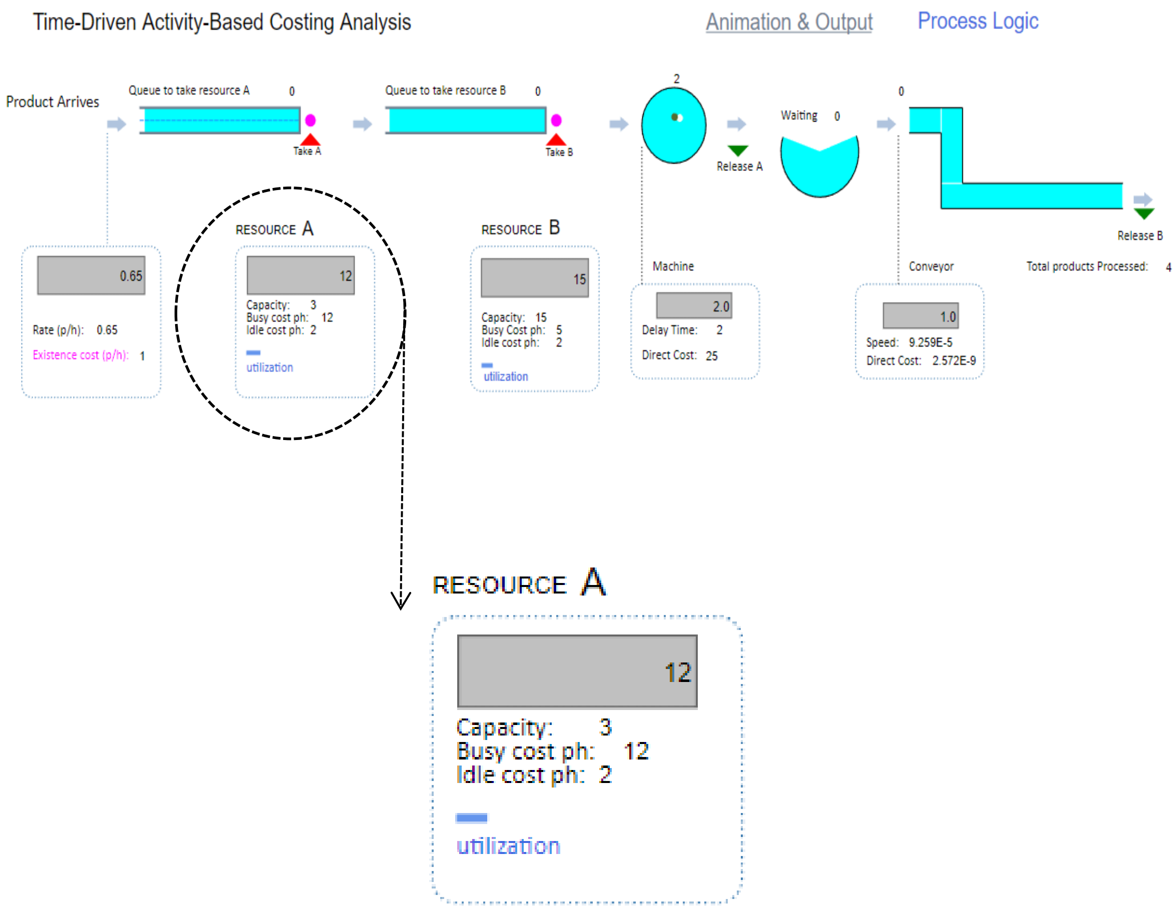


Figure 3.7: Magnified version of textbox

Figure 3.7 shows the digital model of the basic process chain of the physical system and thus as it has a physical counterpart to its virtual replica that receives data from the virtual system it is a digital twin. It shows where the product arrives, where the resources are added to the product, where it is manufactured, where it waits to be shipped, and where it is finally conveyed to be shipped. Below the simulation are small textboxes that contain details about each of the different processes that occur. Figure 3.8 depicts a magnified version of the textboxes. Each textbox's information can be edited to fit the parameters the user requires.

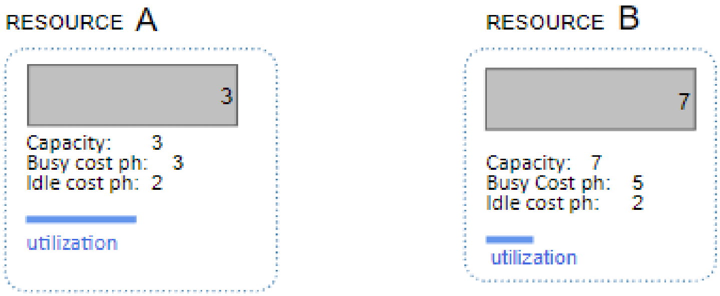


Figure 3.8: Change in resource capacity

The textbox shows the resource, indicating that it has three parameters, namely capacity, busy cost per hour, and idle cost per hour. Above the three parameters is an edit box that is linked to the resource's capacity. This edit box can be changed while the simulation is running, and the rest of the parameters will update automatically. By doing this, the user can see how the different sizes of the capacity parameter affect (possibly) the outcome of the rest of the process chain. It will also immediately show the effect that this parameter has on the busy cost per hour (the cost that is incurred by the busy resource), as well as the idle cost per hour (the cost that is incurred while the resource remains idle). Then the final piece of information that the user sees in this textbox (Figure 3.8) is the utilisation level of the resource. This utilisation level shows the user how much of the resource is being utilised, which can be an indication of how much of the resource remains for the next process. Each textbox is related to a different part of the process chain and each textbox has an edit box that can be used to edit a certain parameter. The parameters can be edited while the simulation is running, and the updated results will be displayed. The user can do this until they have found an optimal solution for their current process needs. By being able to see the costs of certain processes and comparing them to the bar graphs which show the time that is taken by each part of the process, the user can easily see whether the processes that take up the most time are also the processes that cost the most. In this way, a level can be found where both time use and available funds are optimised.

Figure 3.8 above also shows what happens to the busy cost and idle cost per hour as the capacity amounts are adjusted. Immediately, the busy cost per hour reduces as opposed to the amount of time in Figure 3.7. This is because, when then capacity is decreased, fewer resources are available for the manufacturing process. As the level of resources decreases, both the total processing time and the idle times of the machine decreases, this ultimately leads to a lower total cost of the product. By comparing the two runs, the user can identify which factors have the biggest impact on the total cost of the product.

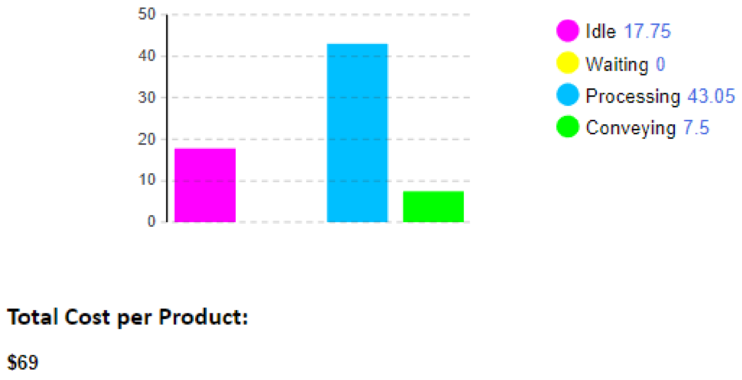


Figure 3.9: Change in cost

Figure 3.9 shows how much time is spent in each section of the machine. As parameters are adjusted, the graph adjusts to show the related results.

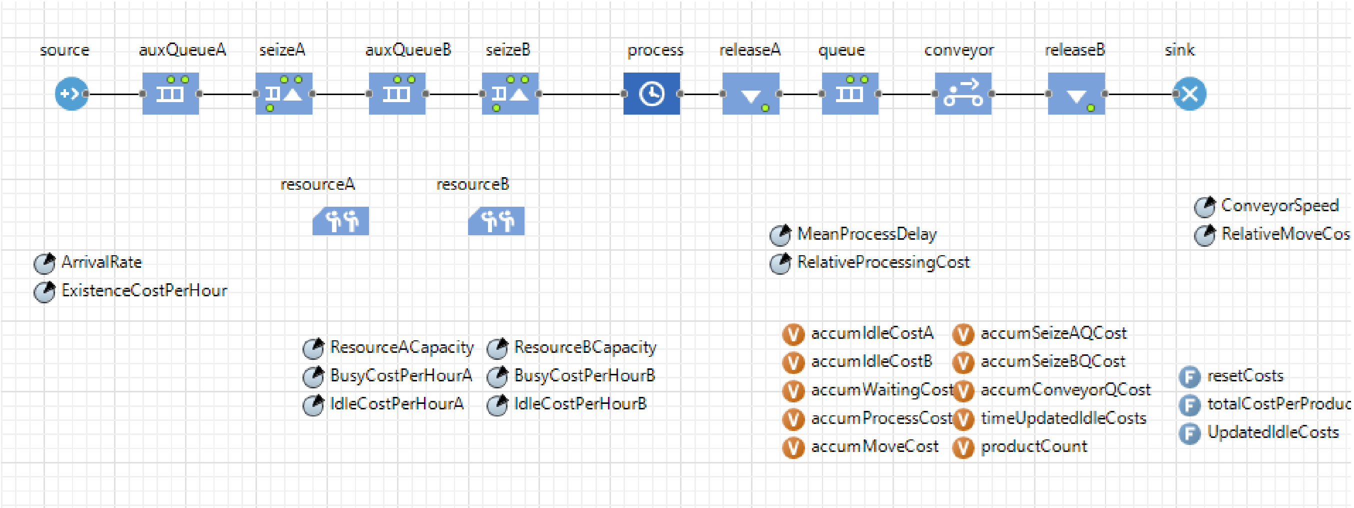


Figure 3.10: Snapshot of the actual building of the simulation

Figure 3.10 shows the back end of the digital twin or the digital twin calibration. If adjustments need to be made to the DT, it is done on the interface shown in Figure 3.10. Figure 3.10 gives a clearer perspective of all the detail involved in the development of a digital twin. As the complexity of the digital twin increases, the calibration complexity and detail levels increase accordingly.

3.4.1.4 Examples of the outcomes when data is altered using Scenario 1

Where does the data come from (possible sources?)

The arrival rate is the rate at which new requests for implants occur. The Resource Capacity at Process A in this scenario is the number of available designers who can work on the implant design. The Capacity for Resource B is the number of prints that can be at the surgeon at a time for him/her to alter using wax until exact specifications are met. Machine Capacity is the number of AM machines that are available/the number of implants that can be manufactured at a time. Conveyor Speed is the time it takes for an implant to reach the customer after the manufacturing has completed. Table 3.1 below shows how the data was altered as the AnyLogic examples ran. The blue blocks indicate which parameters were changed compared to the previous run.

Table 3.1: Table showing the value of each parameter per run

	First run	Second run	Third run	Fourth run	Fifth run
Arrival Rate	0.1	0.1	0.4	1	0.1
Resource A Capacity	1	2	1	1	1
Resource B Capacity	4	4	4	4	4
Machine Capacity	1	1	1	1	2
Conveyor Speed	5	5	2	5	5

Round 1:

The Rate for Scenario 1 will be = 0.1 implants per hour

The Capacity for Resource A = the number of available designers = 1

The Capacity for Resource B = number of prints at the surgeon = 4

Machine Capacity = number of prints that can be printed at a time = 1

Conveyor Speed = time it takes for implant to reach the client after being treated = 5

Table 3.2 below shows how the output results changed as the inputs in Table 3.1 changed.

Table 3.2: Output values per run

Outcome	Existence Cost p/h	Busy Cost p/h	Idle cost p/h	Utilization	Busy Cost p/h	Idle Cost p/h	Utilization	Direct Cost	Direct Cost	Total products processed	Total cost per product
1	1	3	2	high	5	2	low	100	7.5	23	$154
2	1	2	2	medium	5	2	low	100	7.5	23	$174
3	1	1	2	high	5	2	low	100	1.2	23	$123
4	1	1	2	high	5	2	low	100	7.5	23	$131
5	1	3	2	High	5	2	low	25	7.5	23	$119

Round 1 Results:

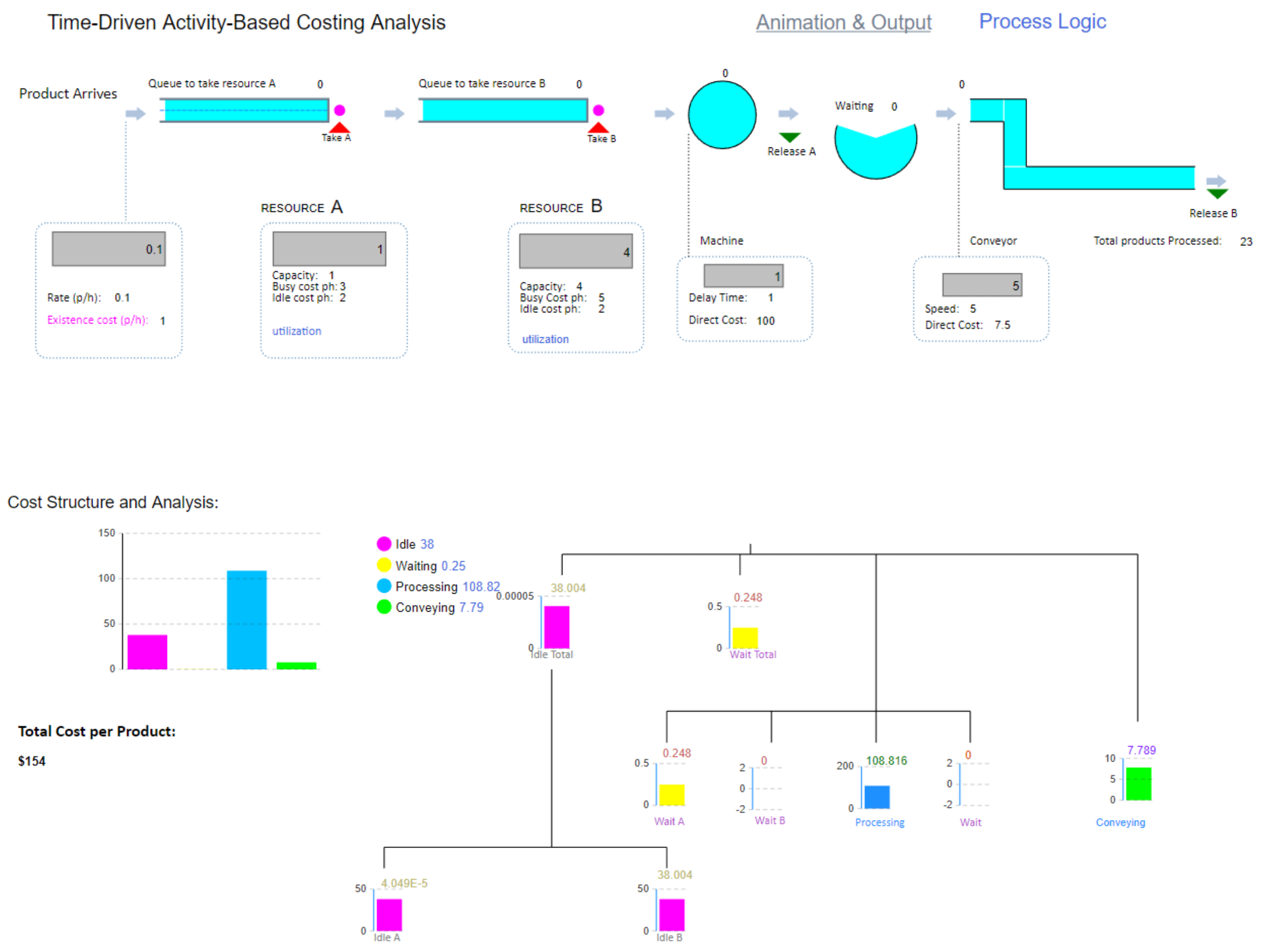


Figure 3.11: Round 1 Results

Figure 3.11 shows Round 1 Results. After the first outcome and looking at the results the researcher could see that the Idle Time is quite high, the waiting time at Resource A is quite high, this is expected as Resource A only has a capacity of 1 and the Processing time is quite high. It is expected that the processing time is high as it takes a while to manufacture the implants.

Round 2 results:

Resource A's Capacity was increased, and the outputs were monitored. Figure 3.12 shows Round 2's results. Idle time has increased as now that there are more designers, designs are completed at a faster pace however there is still only the same amount of capacity available in the rest of the process and so a queue develops. The total cost per product increases as well – this can be because of the cost of the extra designer added.

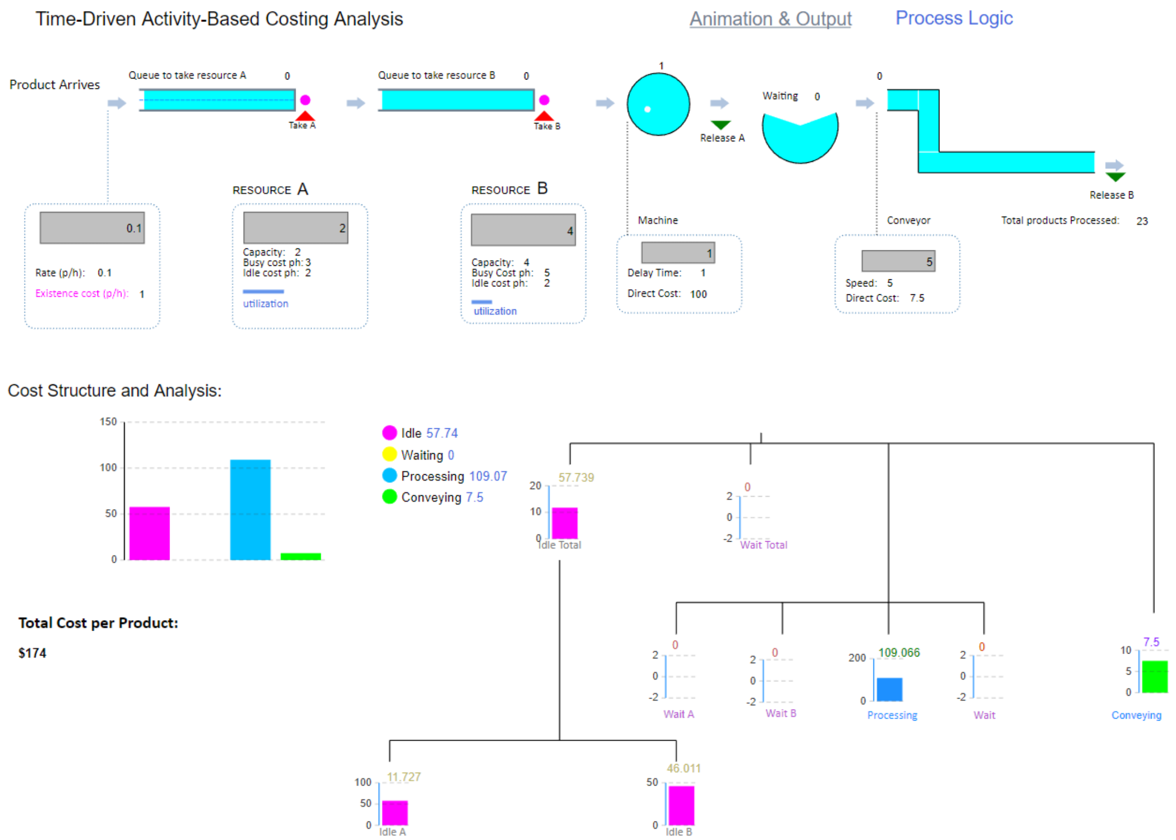


Figure 3.12: Round 2 Results

Round 3 Results:

The researcher then decided to increase the arrival rate, decrease the conveyor speed, and decrease the capacity at resource A. Figure 3.13 shows Round 3's Results. When compared to the previous rounds, the Idle Time has now decreased compared to Rounds 1 & 2. The cost has also decreased due to one less designer being used. Idle time has decreased as the jobs arrive at an increased pace and so the system remains busy. The decreased conveyor speed ensures that there are no idle times as the process never stands still – while products are being manufactured, some are in the post-process phase. Processing time remains constant as the Machine Capacity remains constant.

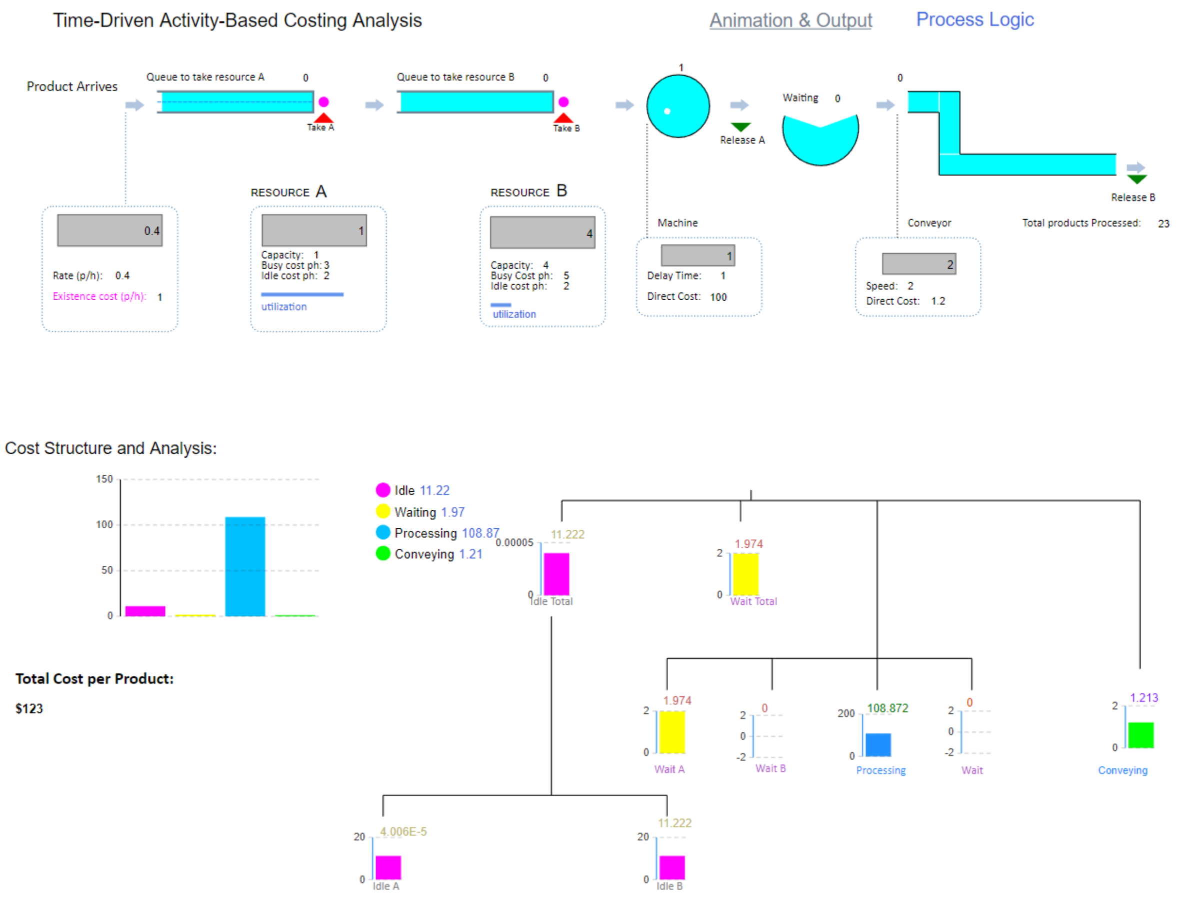


Figure 3.13: Round 3 Results

Round 4 Results:

In Round 4 the conveyor Speed and Arrival Rates were altered. Figure 3.14 shows the results of Round 4. Here, both the arrival rates and conveyor speeds were increased. As products are arriving at such a quick rate, the waiting time increases as the capacity of the process only allows for so much work to be conducted at a time. The cost increases as the efficiency of the process chain decrease. Idle times decrease as the process has no chance to stop at the rate that implant requests arrive. Processing times also increase accordingly.

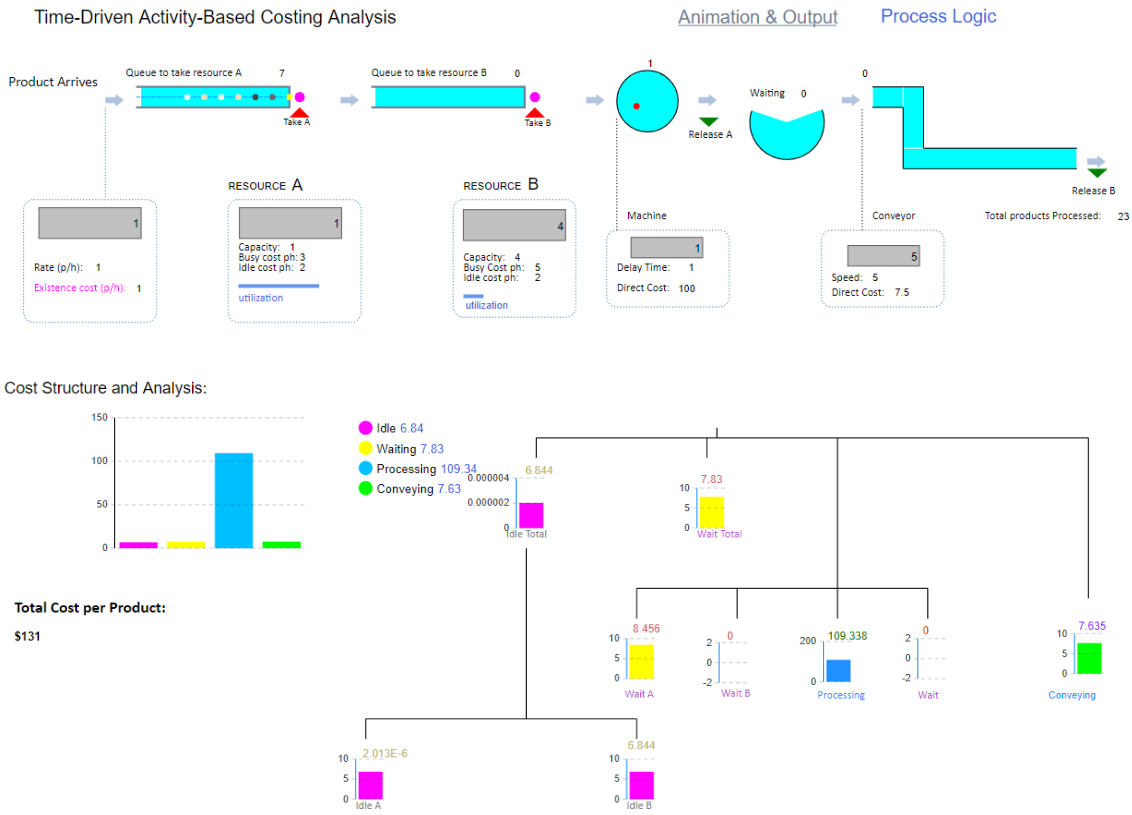


Figure 3.14: Round 4 Results

Round 5 Results:

In Round 5 the arrival rate and machine capacity were altered. Figure 3.15 indicates Round 5's results. There are now double the machines available and implant requests arrive at a much slower pace. The total cost is the least of all rounds. This is due to more machine capacity and thus fewer direct costs involved as now the throughput rate is increased. Idle times are increased as the implant requests arrive at a slower pace and certain processes must wait for work to arrive. Waiting times have decreased as implant requests are less frequent and by the time the requests reach the AM process, the previous/current job is almost complete.

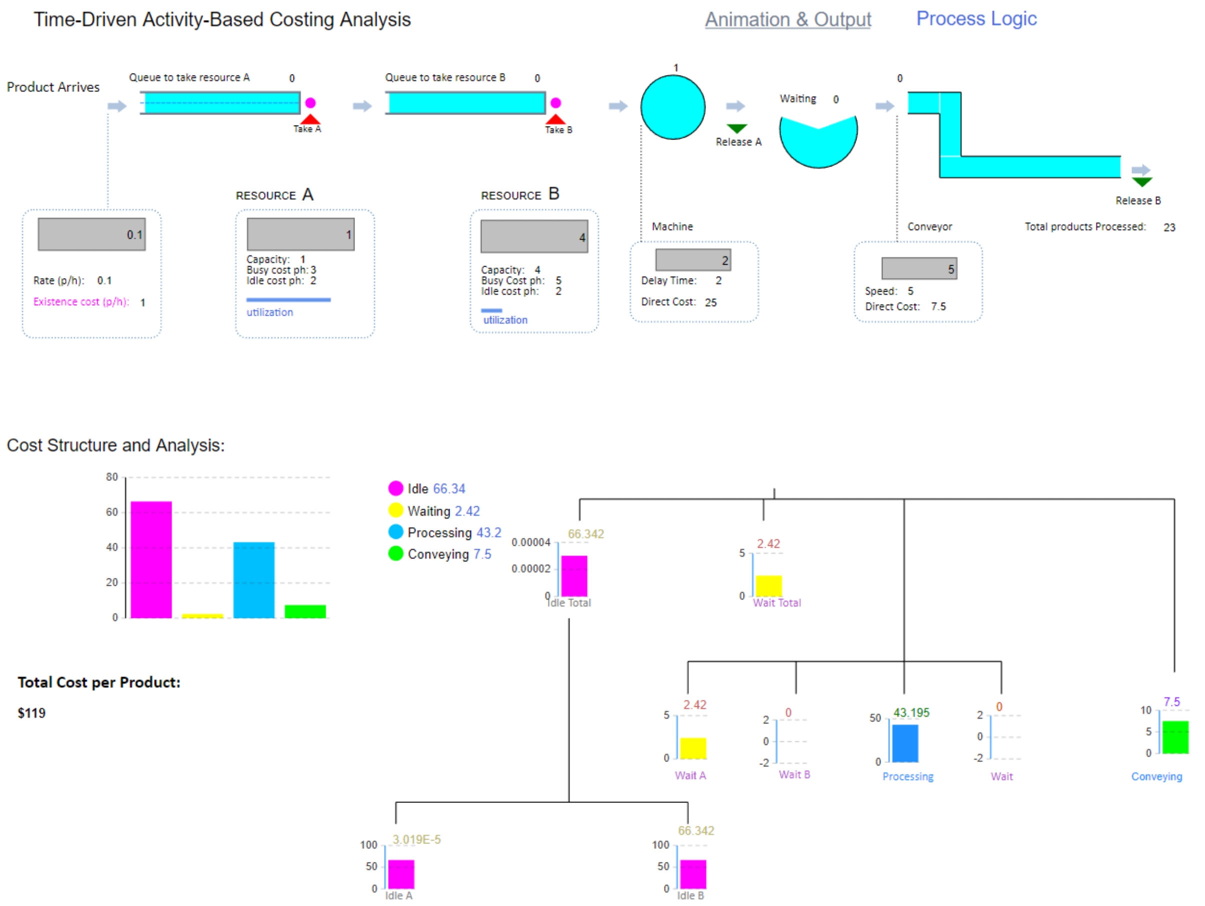


Figure 3.15: Round 5 Results

In the same way as Round 1-5 was conducted, the digital twins can continually run and update in real-time to make future predictions and to adjust accordingly.

3.4.2 AnyLogic Example 2: Factory floor

To understand the factory floor example best, a description of each part is given to show how all the parts work together and to show how customizable the digital twin is. The first part that was built and programmed was the CNC Machine. The CNC Machine was built in such a way that parts get dropped off, the part waits for a machine to become available, then the part moves to the machine, is processed and completed, the part is then sent to a buffer area, when the part is completed, it is moved to the end ready for the next phase.

In addition, the truck, forklifts, the part, pallets, and the moving of the part had to be programmed individually. Each piece of the entire process can be customized to suit business needs. The example can be further developed to become more complex and to integrate with more systems to become a fully functional digital twin. The next example is a basic manufacturing example, as CRPM is not only a research company but also a manufacturing company.

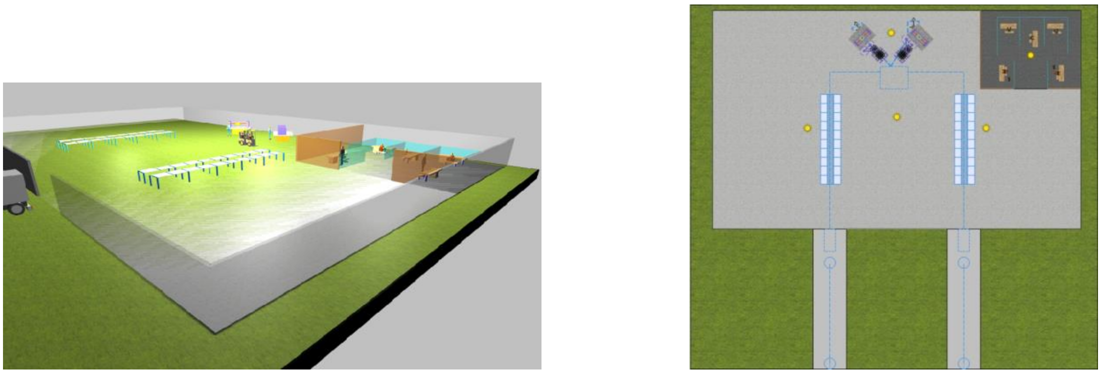


Figure 3.16: 2D & 3D versions of the simulation

Figure 3.16 shows a 3D view of the factory floor. This is a 3D view of when the simulation is run and gives the user an idea of how the actual factory floor will look like or looks like. It, therefore, gives the user perspective. This specific image in Figure 3.16 shows where the offices, pallet racks, and the computerised numerical control (CNC) machines are and shows a small part of the delivery truck that is delivering resources. The process in this factory works as follows: Raw materials arrive via the delivery truck. Forklifts then pick up the raw materials and take it to the pallet racks where they are stored until needed for use. When a job card is opened, the raw materials that are needed are fetched via the forklift and taken to the CNC machine. Here the CNC machine processes the raw materials and manufactures the required product. After a certain amount of time, the manufacturing is completed and the final product is once again fetched by the forklift and stored on pallet racks on the opposite side, where it is kept until it is time for it to be shipped. Figure 3.16 also shows the 2D layout of the factory floor.

In the same way, when a request to additive manufacture a medical implant is received, raw materials are sourced, taken to the additive manufacturing machines, processed, removed from the machine, and sent to be treated (i.e. the waiting time on the pallets after the manufacturing process) and delivered to the customer. Both processes take raw materials and manufacture it into the required part.

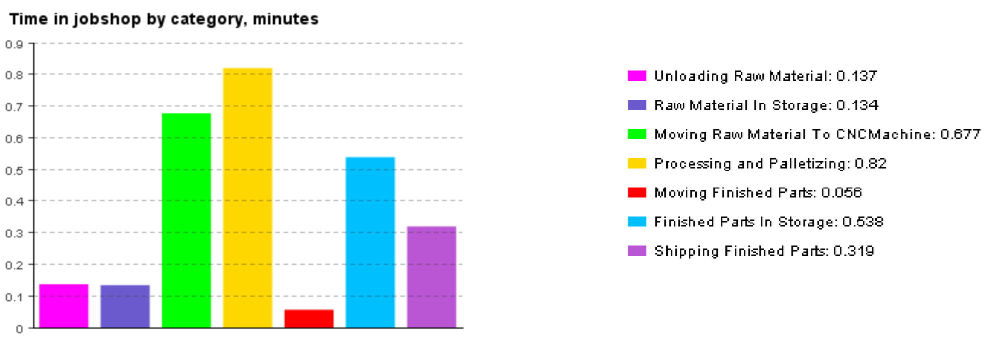


Figure 3.17: Bar graph

Figure 3.17 shows a closer look at the bar graph. This bar graph is obtained once the process has run. This bar graph shows how long each part or 'job' in the process chain takes. By studying this bar graph, the user can see where most time is spent in the process chain. In this case, it is the gold bar that is named 'Processing and Palletizing'. By using logic, it is easy to see how this could be possible. CNC machines need to build or manufacture the product, and, depending on the size, shape, and complexity of the product, this time can differ. When compared to the additive manufacturing process, it is similar as most time is spent in manufacturing the implant.

Figure 3.18 below shows the statistics of the factory floor layout. The statistics include the utilisation of the forklifts, the utilisation of the CNC machines, the time spent in certain states of the manufacturing process. These graphs are also based on the variables within the process. When looking at Figure 3.18 it is evident that the CNC machines both get utilized fully. To see whether a change is possible one could add another CNC machine and see the effects thereafter.

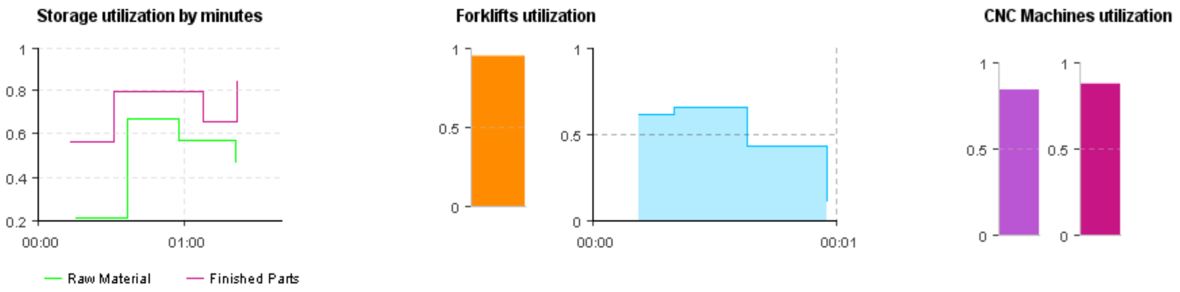


Figure 3.18: Statistics

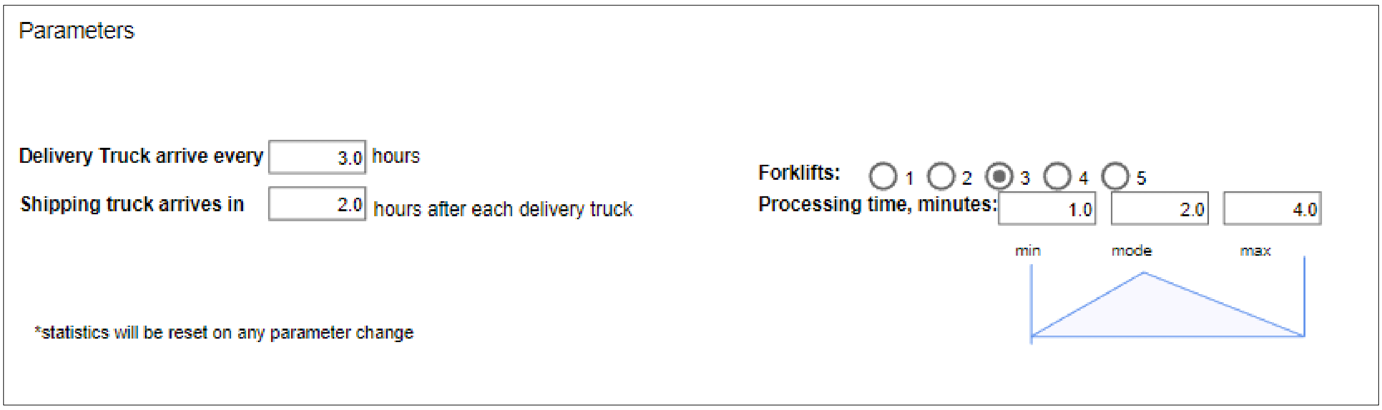


Figure 3.19 Parameters

Figure 3.19 shows more statistics involved with the process chain as well as different parameters. These parameters can be altered as the needs of the business are identified. The parameters above can be changed while the simulation is run, and then the effects of these changes can be examined on the charts in both Figure 3.17 and Figure 3.18. This is a simple way of determining the effect of different parameters on different parts of the process chain. It can also be used as a tool to identify where problem areas are and what might cause these problems.

Figure 3.20 gives a small insight into the behind-the-scenes development and shows just how complex these simulations can become. Once again, the integrity of the data used is confirmed to be highly important. As soon as one process is altered in real-time, the simulation is also adjusted

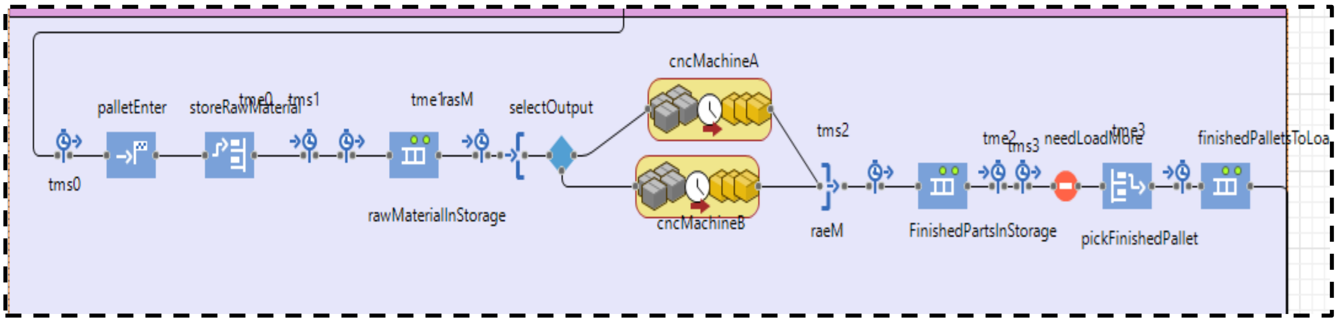


Figure 3.20: Manufacturing process

Table 3.3 below shows how the parameters changed for the manufacturing example. In Round 2 forklifts were added to see what the result would be.

Table 3.3: Iterations of manufacturing example

	Round 1:	Round 2:
Delivery Truck Arrival Rate	3 hours	3
Shipping Truck	2 hours	2
Forklifts	3	5
Processing Time (min, mode, max)	1;2;4	1;2;4

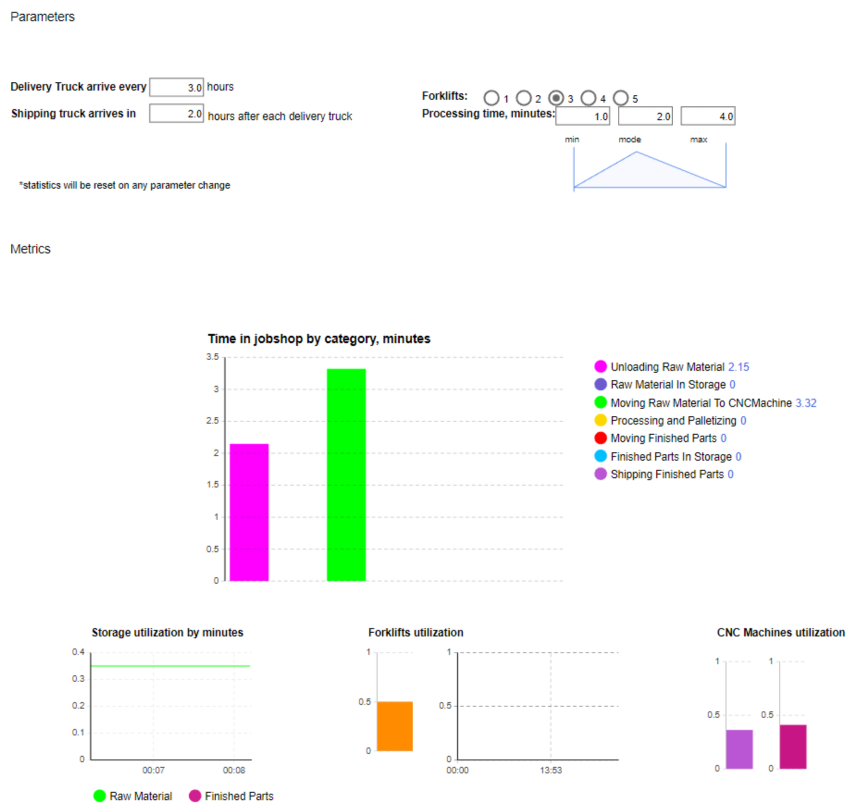


Figure 3.21: Round 1 Results

Figure 3.21 shows the first round's results. After the first round, it is evident that the most time is spent in moving resources to the CNC Machines and the Forklifts and CNC Machines are not utilised fully. In Round 2 the number of forklifts was increased and the effects were viewed. In Figure 3.22 below it is evident that as there are more forklifts to move raw materials, the raw materials reach the CNC machines quicker and they are utilized fully.

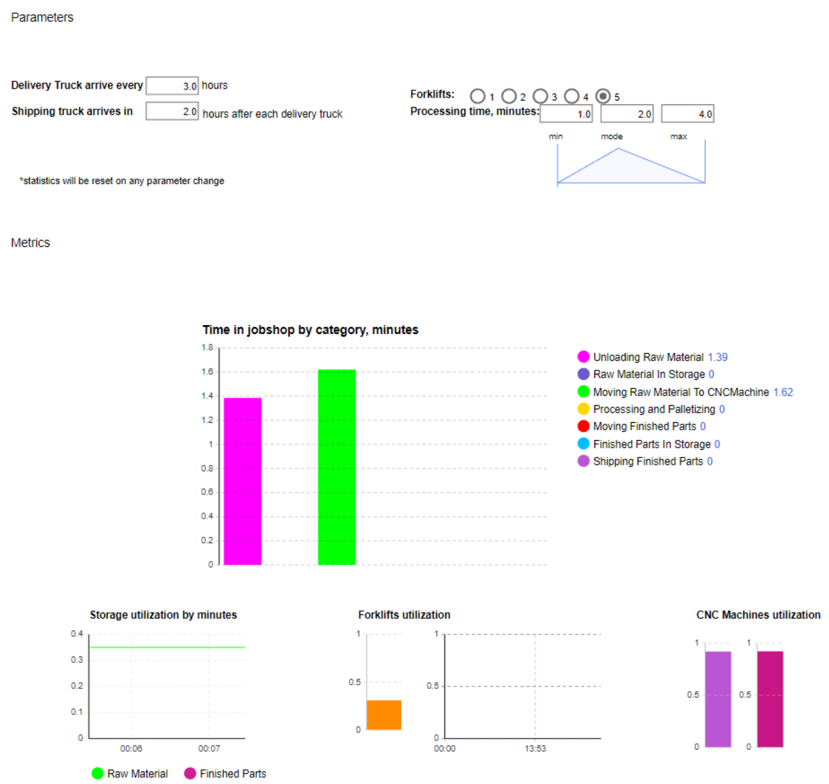


Figure 3.22: Round 2 Results

As time is used more effectively by increasing the speed at which products are moved through the process chain, the utilization levels of the machines are increased, and less time is wasted in idle positions or during sub-processes. The digital twin helps one to see the effects of the data on the results. Both digital twins are still in their development and early stages. However, the iterations done show the effect of digital twins as the effects of each small change can be seen with regards to cost and time. On first look, it seems as if it is a simulation, however, it is an iterative process that updates as real-time data is entered and the effects are observed. One can now employ predictive algorithms which suggest new values for each of the parameters as time passes, automatically. However, these predictive algorithms are currently outside of the scope of the research.

3.4.3 Major challenges in building digital twins

SOPs are specific to an operation and describe the activities necessary to complete tasks. SOPs are in accordance with industry regulations, laws, and a company's standards. Most sub-processes of a process chain of an AM business have predetermined and pre-defined SOP's associated with it. It is crucial to complete SOPs effectively, but this does take up time. They, therefore, need to be incorporated into the digital twin. An example of a SOP at CRPM is the preparation that takes place before a part can be printed. Table 3.4 shows this example SOP. Simulating each of these steps accurately becomes complex. However, in the above example, it is assumed that the preparation of the machine occurs while the process is in the phase before machining (simultaneously).

The current build of these simulations only shows the shell of these processes, but to ensure that the results are usable, more intricate details such as the SOPs associated with each process should be added. SOPs ensure that a certain process is always executed in a specific manner. They also exist to remind employees who are completing a certain task what they need to do and therefore prevent confusion. Incorporating SOPs into the digital twins will allow for more accurate results. However, it becomes a complex task, since many SOPs do not have standard times associated with them and thus the effect that they have on the entire process may vary. Other processes which need to be considered are the design phase, the planning phase, and outsourcing. Each part that needs to be incorporated into the simulations requires time, planning, and research. Thus, experts in the software will probably need to be used. Using the software requires both knowledge of programming and training in the specific software. While developing these examples, a lot of trial and error took place, for a new user it takes time and is an iterative process. Having an expert IT Team in place is thus crucial for the successful development and implementation of such technologies.

Table 3.4: Example SOP

Step	Action	Complete:
1.	Put on protective gear, which includes an overall, safety goggles, gloves, and a gas mask.	
2.	Ensure the machine is switched off.	
3.	Open the machine and remove all excess powder that is left over from the previous job.	
4.	Use a vacuum cleaner to suck up all remaining powder particles all over the printing area of the machine.	
5.	Remove the brushes used to brush the next layer of powder over the print job and clean.	
6.	Insert the correct brush or steel plate that is necessary for the next print.	
7.	Insert a new or cleaned printing platform.	
8.	Calibrate the machine to the correct settings for the next printing job.	

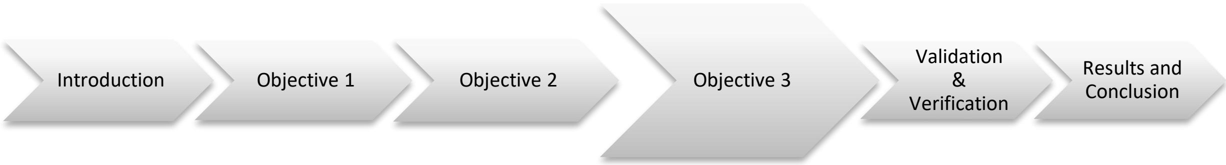
Often the available software poses challenges. Software licences and packages can be quite expensive, and it should be weighed up whether it will be worth the cost.

Another factor that increases the complexity of the development of digital twins is standard times. It is important to determine the standard times of the sub-processes in the process chain. Once these standard times are known, one can measure where the process is currently operating, after which the digital twin can be used to drive the processes to these standard times. However, calculating the exact standard time of each process, sub-process or event may be quite a tedious and complex task. A business can determine what they need to do to ensure they reach and uphold these standard times. Standard time is what management strives to achieve and a digital twin can help with this. However, to achieve this, every possible factor that could influence these times need to be simulated and built into the digital twin. Once again, this can become a very complex problem.

3.5 Summary of Objective 2

Objective two provided insight into what is required to develop a digital twin. Objective two explained the different levels and different types of digital twins that can be created. Five steps or building blocks were introduced and which need to be followed when developing a digital twin. Before commencing with the build of the digital twin, the design step must be completed. Each step must be completed before the next phase can be put into action. The digital twin created in Objective 2 is a combination of a Level 1 and Level 2 Digital twins, meaning that they are a combination of data and simulations to view a business process. Objective 2 outlined what it takes to build a digital twin and what the implications are regarding the building and implementation process. Multiple runs on both digital twin models were done to display how time can be optimised at CRPM as all planning can now be done ahead of time. The result of each run could be used to plan the next run and decisions can be made before the actual process occurs. In this way, CRPM can model possible problems and see the effects that they have on the system and their costs. SOP's do have an impact on the digital twin and entire process, and this was made clear in the objective. The power and adaptability of a digital twin were emphasized.

4 CHAPTER 4 – OBJECTIVE 3: INTEGRATING THE DIGITAL TWIN FOR BUSINESS



During this Objective, the student will apply the knowledge from Objective 1 & 2. Chapter 4 seeks to investigate and determine Objective 3: Integrating the digital twin for business. The knowledge gained in Objectives 2 & 3 are combined into determining Objective 3. This objective seeks to show how a digital twin will be advantageous for a manufacturing company such as CRPM by using a decision-making model.

4.1 Literature

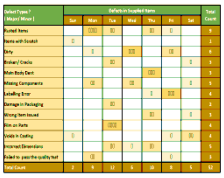
4.1.1 Business integration

The goal of business integration is to synchronise information technology (IT) and business cultures and objectives and align technology with business strategy and goals. Business integration reflects how IT is being absorbed into a business and involves sustainable, viable, and quality IT integration. Sustainability means that something can be maintained at a certain rate or level, while viability refers to the ability to work successfully. Quality is the standard of something as measured against other things of a similar kind; it is the degree of excellence of something. It is necessary to keep the idea of business integration in the back of one's mind when wanting to apply digital twins within a business.

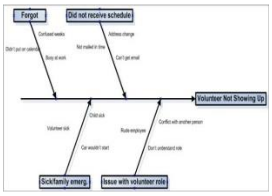
4.1.2 Basic quality tools

The ability to identify and resolve quality-related issues quickly and efficiently is essential to anyone working in quality assurance or concerned with process improvement. A set of seven quality tools were developed by Kaoru Ishikawa, a Japanese professor of engineering. These quality tools, implemented by Japan's industrial training programme during the country's post-war period, were turned into statistical quality control measures for quality assurance. The goal was to implement basic, user-friendly tools that workers from varied backgrounds with varied skillsets could implement without needing extensive training. Today, these quality management tools are still considered the gold standard for troubleshooting a variety of quality issues. They are frequently implemented in conjunction with today's most widely used process improvement methodologies, including various phases of Six Sigma, TQM, continuous improvement processes, and Lean management. These seven statistical quality control measures are outlined below.

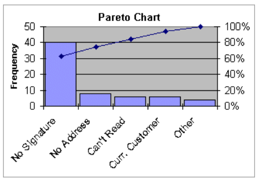
Histogram: Helps to represent frequency distribution of data clearly and concisely amongst different groups of a sample, allowing one to quickly and easily identify areas that need improvement within the business.



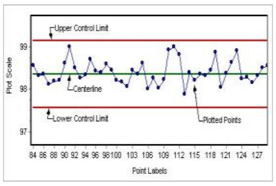
Check/tally sheet: Check sheets can be used to collect data. When used to collect quantitative data, they can be called a tally sheet. A check sheet collects data in the form of check or tally marks that indicate how many times a particular value has occurred, allowing one to quickly zero in on defects or errors within the process or product, defect patterns, and even causes of specific defects.



Cause and effect diagram: Introduced by Kaoru Ishikawa, the [fishbone diagram]() helps users to identify the various factors (or causes) leading to an effect, usually depicted as a problem to be solved. Named for its resemblance to a fishbone, this quality management tool works by defining a quality-related problem on the right-hand side of the diagram, with individual root causes and sub-causes branching off to its left.

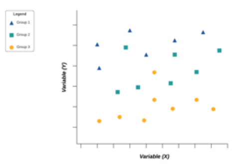


Pareto chart: The goal of the Pareto chart is to highlight the relative importance of a variety of parameters, allowing one to identify and focus one's efforts on the factors that have the biggest impact on a specific part of a process or system.



Control chart: Control charts use a central line to depict an average or mean, as well as an upper and lower line to depict upper and lower control limits based on historical data. By comparing historical data to data collected from the current process, one can determine whether the current process is controlled or affected by specific variations.

Scatter diagram: The scatter diagram is most useful in depicting the relationship between two variables, which is ideal for quality assurance professionals trying to identify cause and effect relationships.



Stratification: Quality assurance tool used to sort data, objects, and people into separate and distinct groups.

4.1.3 Digital twin decoupled

Digital twins were proposed and adopted by NASA. They used it for monitoring and optimisation of safety and reliability optimisations of spacecraft (Grieves, 2014) & (Boschert & Rosen, 2016; Brenner & Hummel, 2017; Grieves, 2014). The digital twin vision refers to a comprehensive physical and functional description of a component, product, or system (Tuegel, Ingraffea, Eason & Spottswood, 2011), which includes all information that could be useful in the current and subsequent lifecycle phases. Simulation and the seamless transfer of data from one life cycle phase to the subsequent phase is the core of the digital twin vision.

Two typical understandings/areas of the digital twin can be observed in industrial practice (Rosen, Wichert, Lo & Bettenhausen, 2015). In the production design area, companies increasingly use complex product models to boost the immersion in virtual and augmented reality applications (Knapp, 2017). TESLA aims at developing a digital twin for every built car, hence enabling synchronous data transmission between the car and the factory, whereas Dassault strives for the product design performance. In the system management area (Reifsnider & Majumdar, 2013), General Electric emphasises forecasting the health and performance of their products over the lifetime (Seshardi, 2017), while SIEMENS focuses on establishing a connection between the virtual model and the physical part for improving efficiency and quality in manufacturing.

4.1.4 Technical versus commercial feasibility

Technical feasibility assesses the details of how it is intended to deliver a product or service to customers. Think materials, labour, transportation, where the business will be located, and the technology that will be necessary to bring all this together. It is the logistical or tactical plan of how the business will produce, store, deliver and track its products or services.

A technical feasibility study is an excellent tool for both troubleshooting and long-term planning. It can serve as a flowchart of how products and services evolve and move through a business to physically reach the market. Commercial feasibility typically covers the amount of investment that is required to bring the innovation to the market; the approach to secure the required investments; the commercialisation strategy and the revenue model.

According to the Playvox website, an easy method to optimise a quality assurance programme is to introduce a real-time agent data. By getting data or information on the business' agents in real-time provides one with insight into performance mistakes without needing to wait for data to be analysed every three to six months.

4.1.5 Technological advancements and the process chain

AM, in conjunction with other technologies, can be used to significantly shorten product development times and costs (Sinding, Waldstor, Krietner & Kinicki, 2014). AM allows process chains to be optimised and waste and variation to be reduced and change management strategies facilitate any needed changes to the process chain. Technological automation can be seen as manufacturing automation or office automation, both advancing the steps in a process chain and striving to optimise the flow of the process chain. Technological advances occur when manufacturing and service organisations increasingly use technology to improve productivity and market competitiveness. Manufacturing companies automate their systems using technology such as CNC, which is used for many manufacturing operations, and CAD. Companies also use computer-integrated manufacturing. Office automation consists of hosts of computerised technologies that are used to obtain, store, analyse, retrieve, and communicate information. IT-driven changes feed back into demographics, in the sense that traditional skills become less attractive unless they are matched by improved IT skills. IT changes organisations because business models, marketing methods, service practices, sales channels, and manufacturing operations all change (Sinding, Waldstor, Krietner & Kinicki, 2014). Digital twinning is seen as a technological advancement (Ferguson, 2017).

4.2 Methodology

For each factor that is added to the digital twin, each detail needs to be programmed and simulated into the entire process. Every SOP makes a difference to the amount of time both a process takes and the amount of detail that has to be built into a digital twin for the digital twin to be accurate. We want to reduce cost in the end and thus we want to simplify the SOP procedure as much as possible to make the integration into the digital twin simpler. We need to refer to the research question: is a digital twin a possible tool to use to optimise an AM business? When considering how large and complex a detailed digital twin of CRPM would become, we must determine what is important, what we really influence, and what we can drive down. The research was conducted in the order indicated below.

1. Decouple a digital twin
2. Propose a decision-making tool for digital twinning
3. Apply the decision-making tool

4.3 Research and findings

From Objective 2 it is evident that building a digital twin of a process such as the AM process quickly becomes a complex task. The more accurate the results must be, the more detailed the digital twin needs to be. To understand how the digital twin relates to CRPM, the digital twin needs to be broken down into separate levels. In this research, the objective is to determine whether a digital twin will be able to aid in optimising time usage for AM businesses. The individualised design of each medical implant in the production line presents distinctive characteristics due to the personalised needs of the implants, including the diversification of the design, a difference of the production capacity, the constraint of production costs, and integration of various types of equipment (Koren & Shpitalni, 2010; Gu, Hashemian & Nee, 2004). The design objective is to reduce the time to production and increase efficiency during the operations. The biggest and possibly most complicated question to answer is: How do I get from the physical layer to the quantification of the physical layer? A possible answer to this question is the concept of digital twinning. A digital twin needs to be adaptable. Ensuring that a digital twin can dynamically adapt involves a lot of complexity and difficulty, and thus decoupling the process of creating a digital twin is a promising approach, as now nothing is unknown, and all steps are laid out clearly.

In this section, we will look at an input-process-output view of digital twin-based design. The AM process of medical implants consists of several processes (Campbell, De Beer, Pei, 2011). It starts with the design of the product using CT/MRI scans, the printing of preoperative models, revisions, and changes of the models by surgeons, alterations of the design, and then finally the manufacture of the actual implant via AM, usually with laser sintering machines. This involves the set-up of the machines, load of raw materials, and the design and the making of the print. Afterward, the print and supports are removed, and post-processing occurs. There is little time available between prints and that capacity balance and utilization ratio should be optimised. The absence or failure of a print can cause production chaos as a new time slot would need to be scheduled for the part, which will reduce the business' production efficiency. Thus, the objective remains time optimisation and increased efficiency during production.

Figure 4.1 below shows that the input of a design includes individualised parameters and variables. The process of design includes equipment configuration and execution system design. The final output of the design is the static physical model, execution system prototype, and the data acquisition system. Because the AM process is constantly changed as individualised designs are executed, two important conditions have to be imbedded in the production line: the first is that there should be some level of flexibility in the static physical model in terms of single equipment type selection, customised prints and capacity demand, and the second is that the execution is dynamic, so the difference in configuration will cause fluctuation in manufacturing efficiency. The execution engine must therefore be compatible with this difference in order to be able to adapt, adjust and optimise. Because every print differs, each process will differ slightly. Some aspects will remain the same and the rest will have to adapt. It is important to plan for all different processes. The figure below is the basis or foundation of the digital twin. The items listed in this figure should be included in the digital twin or are the outline of the digital twin. Details may change, but these core items should remain constant. Analysing and acquiring the data in the figure below is the primary step for creating the digital twin.

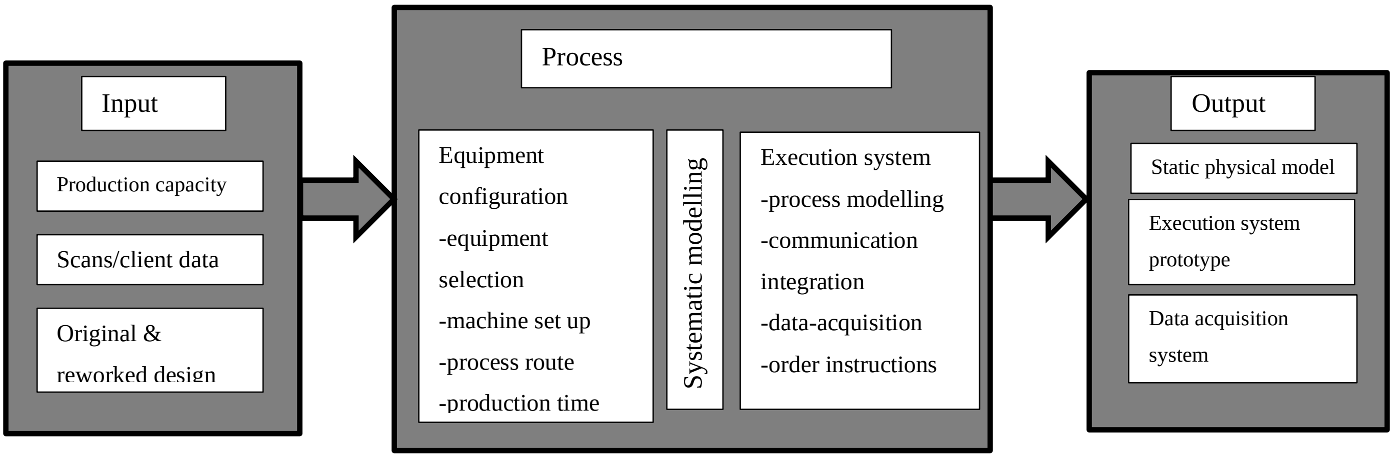


Figure 4.1: Input-process-output

The creation of a digital twin differs from business to business, as it is solely based on the specific business' needs and budgetary constraints; this is also mentioned in Step 5 in Figure 3.1 in Objective 2. One also needs to consider the technology available or technological platforms at a certain business as well as their willingness to adapt. As a digital twin is a fairly new concept, employers as well as employees need to be willing to learn to use a digital twin and what its benefits are.

4.4 Results

The results section will provide a decision-making tool for the user to help them determine if a digital twin is a suitable option for the problem at hand. Using/starting to use digital twins have many challenges, one of the main, if not the main challenge would be to convince an IT organisation that is used to thinking of things in different systems and solutions to take on this task. The second challenge is deciding on the problem to solve. A company needs to have a starting point and then build from there. The decision-making tool aids the company/potential user to be able to decide whether or not to use a digital twin and also acts as a starting point as the user will be able to determine if digital twinning is a suitable route to follow.

4.4.1 **Proposing a decision-making tool**

To ensure that a digital twin is an appropriate tool for a particular company, a decision-making tool is proposed. This tool will guide the user through a certain number of steps to determine what quality tool would be best (a digital twin or another tool). The decision-making tool consists of a flowchart (which is also seen to be a quality tool in some cases) which the user works through to find the optimal tool. Figure 4.2-4.4 below depicts the decision-making tool. A clearer, more comprehensive view of the tool can be found in Appendix E. In the section represented by Figure 4.2 below, the user will be prompted to either investigate a basic quality tool or look at alternative solutions. By using the decision-making tool below, the user can either find a simple solution to the problem that needs to be identified; alternatively, if the issue is more complex, the business unit will meet to further the requirements of the improvement needed or the issue which needs to be addressed. Figure 4.2 shows the starting point of the decision-making tool. Here the general goal for improvement is determined and the project manager will decide if there is an existing solution (i.e., problem can easily be solved with an existing quality tool).

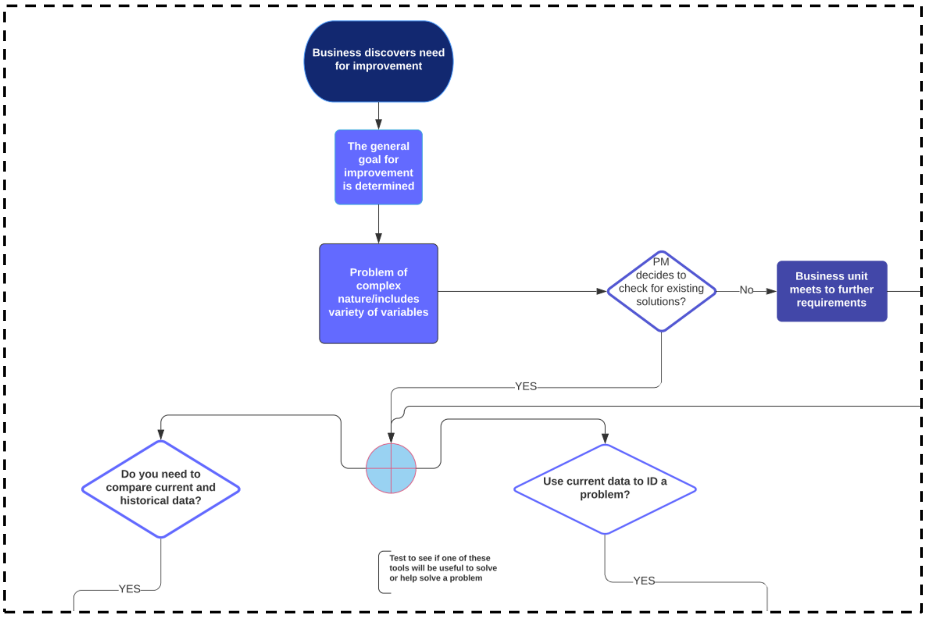


Figure 4.2: Start of decision making tool

Figure 4.3 below shows the route the user will take if the problem to be solved is quite complex and should the project manager decide to opt for further investigation into digital options. Once the business unit has clarified the improvement requirements, the project manager will then create a summary of these requirements. The requirements are then compared to the 5 bullet points to further narrow down possible solutions. Should the general improvement requirements align with the 5 bullet points, the “Yes” path will be followed, if not, the “No” path will be followed. Should the “Yes” path be followed, the requirements will be tested to see if they need to use data to make predictions. If the “No” branch is followed, alternative solutions will be investigated, or the PM will revert to basic quality tools.

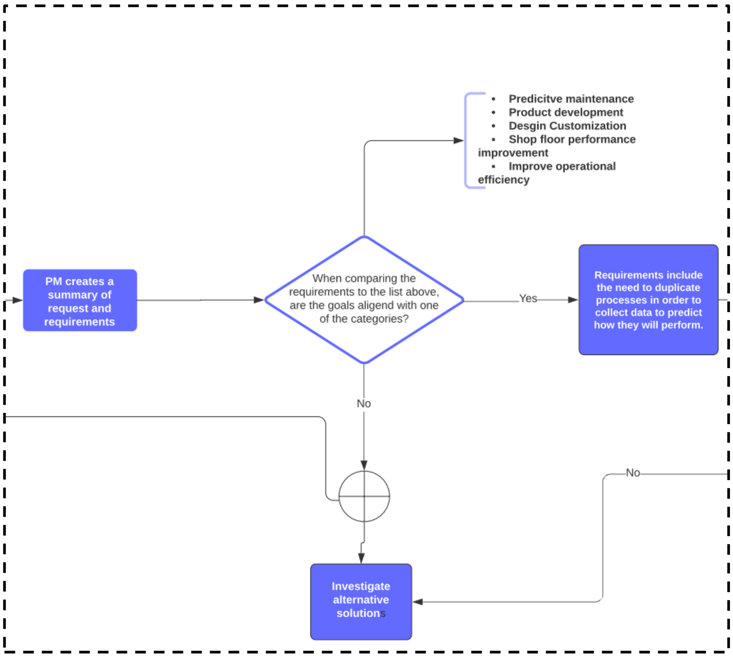


Figure 4.3: Detailed steps to follow once complexity of problem has been proven

Figure 4.4 shows another snippet of the decision-making tool. Once it has been decided that a more complex tool is needed, the user will follow the steps in Figure 4.4. Once it has been established that the improvement will require some sort of data to be used to make future predictions, a digital twin can be investigated. Should the business have or have the funds to invest in all 4 bullets listed, IT will analyse top digital twinning software’s based on the requirements and price range. If not, alternative solutions will have to be found or basic quality tools will have to be used. A more comprehensive view of the decision-making tool can be found in Appendix E. Figure 4.4 includes a step where the IT Team creates a proposal for the digital twin. If it is accepted, the initialisation or the build of the digital twin will commence, if not, the digital twin research stops.

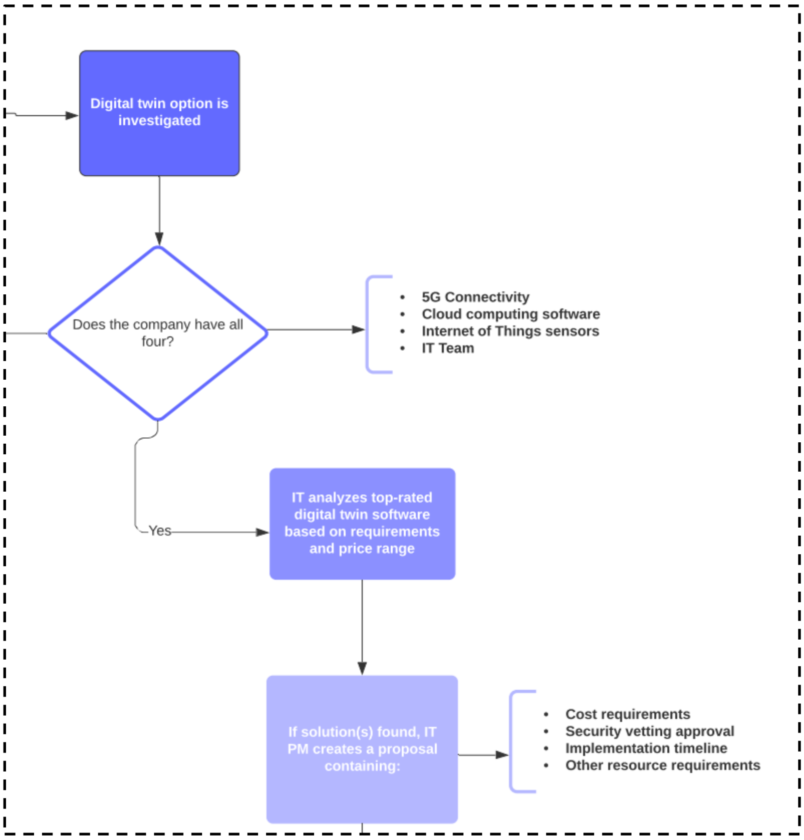
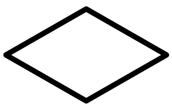
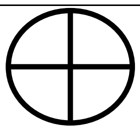


Figure 4.4: Snippet of the decision-making tool

Table 4.1 below provides a key to the decision-making tool, to ensure that the user is clear on what each step means and that any acronyms that were used are provided. It is important to note that the decision-making tool is not final and can be adjusted to ensure that it is more accurate and reliable. As it is used, areas in need of improvement might arise, and they can be adjusted accordingly.

Table 4.1: Key for the decision-making tool

	Process
	Decision
	Terminator
	Or

4.4.2 The application of the decision-making tool

In CRPM, the tool can be used in a simple way or can be expanded, and the detail that one can go into seems endless. For explanation purposes, the researcher applied the tool to the six main processes that occur at CRPM, namely sales, implant design, AM process of the prosthesis, preliminary inspection, final quality checks, and dispatch. One can take it further and break the six main processes into its sub-processes and evaluate each one separately. It all depends on what the goals of the business are. For CRPM, the overall goal is to optimise the use of time and money while keeping the standard of quality at the desired level. The researcher used the as-is vs. to-be table that was drawn up in Chapter 2: Objective 1. Table 2.2 showed which processes needed improvement and what the general goal of each process was. These are the first two steps of the decision-making tool. The next step will be where the problem is evaluated to see if it is complex and thereafter the PM decides that they will investigate existing solutions or whether they can immediately see that the problem is too complex and should go another route. If the answer is yes to existing solutions, the PM will determine if one or more of the basic quality tools can be used to solve a problem. If not, the business unit will meet to further expand on the requirements of the improvement needed. Once these requirements have been finalized, they will be tested against the 5 bullet points to see if the goal of the improvement aligns with one of the bullet points, namely:

- Predictive maintenance
- Product development
- Design customization
- Shop floor performance improvement
- Improvement of operational efficiency

If the goal of the improvement falls in one of these categories, and the requirements include the need to use data to predict future activities, the digital twin option will be investigated. If not, alternative solutions will be investigated. However, should it be decided that a digital twin is investigated; the company will now need access to or at least plan on investing in the following:

- 5G connectivity – digital twins rely on these connections to run
- Cloud computing software – used to develop the digital twin
- IoT sensors – data is collected by these sensors and fed into the digital twin
- IT Team – they will need to run, maintain and apply the digital twin

Should the company not comply with these, alternative tools will have to be investigated. If yes, IT will investigate digital twinning software within the company's price range and depending on their requirements. Thereafter a proposal should be created to ensure that there is a set timeline, cost requirements are met and that a plan of action is set. Should this proposal be accepted, the digital development will be initiated. If not, the procurement will end, and the process can start again should new improvement requirements be set.

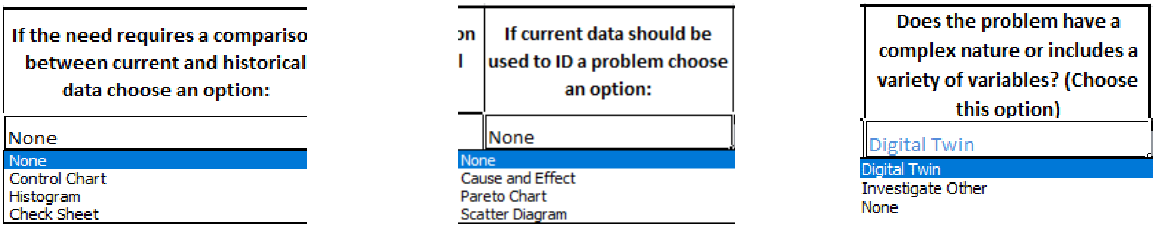


Figure 4.5: Drop-down lists

Table 4.2 below shows a summary of the six main processes at CRPM applied to the decision-making tool. The table allows the user to choose an option in the last three columns from the drop-down lists that are shown in Figure 4.5 below. Table 4.2, the drop-down lists below, and the decision-making tool help the user to quickly identify what would work for which process/problem in a process and to record the data in one place. Each option is colour-coded, meaning that each time the digital twin option is used, the blue colour will appear, and so it will be easy to identify which tool will be used the most.

Table 4.2: Summary of tool use 1

Process	Need for improvement (Y/N)	General goal	Project manager decides to check for existing solutions?	If the need requires a comparison between current and historical data choose an option:	If current data should be used to ID a problem choose an option:	Does the problem have a complex nature or includes a variety of variables? (Choose this option)
Sales process	Yes	Optimise the time taken do activities manually, try save time were possible. Possibly automate?	No	None	None	Digital Twin
Implant design	Yes	Have more plans in place for when surgeons take longer to reutrn pre operative models.	No	None	None	Digital Twin
Additive manufacturing of prosthesis	Yes	Ensure pre-planning is done extensively to acconunt for down time/ prints that don't work.	No	None	None	Digital Twin
Preliminary inspection	No	Can record ductility test numbers to see if there are changes	Yes	Control Chart	None	None
Final quality checks	No	None	No	None	None	None
Dispatch	No	Record number of successes and if unsuccesful what is cause	Yes	Check Sheet	Pareto Chart	None

4.4.2.1 The decision-making tool applied to a more specific process:

To continue the explanation, let us look at the Additive Manufacturing of the Medical Implant process (the actual 3D printing process). The company does not have a lot of control over this process once it has been initiated and it is mostly a waiting period. However, CRPM decides that they want to be able to schedule when maintenance should occur or in other words, they want to do predictive maintenance and not have unscheduled maintenance periods. They have also decided they want to know how the printing process alters for each implant that needs to be manufactured (i.e., see how the cost and printing time changes regarding different materials, sizes of implants or even complexity). Here CRPM have identified a need for improvement and the improvement consists of a variety of variables. Immediately it can be seen that the problem is to complex for the basic quality tools. The list of requirements is then setup:

1. Want to be able to predict when maintenance should occur
2. Monitor how times and costs change as different parameters are altered

When these two requirements are compared to the 5 bullet points, they align with the following:

- Predictive maintenance – Yes
- Product development -Yes
- Design customization - Yes
- Shop floor performance improvement
- Improvement of operational efficiency – Yes as the results obtained will be used to make improved decisions

These two requirements will require data observed over a period of time to predict future processes. Thus, a digital twin will be investigated.

CRPM does have access to 5G connectivity as they deal with various complex software programs, work mainly if not only on the internet and most of their processes are online. CRPM also has a dedicated IT Team. IoT sensors will be invested in once the digital twin development is initiated and Cloud computing already exists within the company. IT now analyses top-rated digital twin software within CRPM's price range (in the case of the research Anylogic was found to be the best for free use and for what was needed to be achieved). The digital twin development could then occur. Now the 5 steps mentioned in Objective 2 Figure 3.1 can be applied. The decision-making tool also helps the company to decide what the criteria of the digital twin should be as one now determines what the digital twin should help achieve or improve on (Step 5, Figure 3.1).

4.4.2.2 The decision-making tool applied to other sub-processes in the process chain

To continue the explanation, let us look at the first process at CRPM, which is the sales process. The sales process as mentioned in Chapter 2 in Table 2.2 consists of new customers that are added to the system and the creation of a unique ID for each customer. CT/MRI scans are made for the customer to determine the extent of the issue. The CT/MRI scans are used by the design team to start developing a plan of action and identify the risks involved. The CT/MRI data is converted to STL format and can now be designed or edited using CAD. The STL format also indicates how much of which resource should be used, and thus costs are estimated for the project. A quote and indemnity form will be sent to the customer, and it will either be approved, and the order will be placed, or it will be discarded. CRPM updates their order book and can now complete a job card.

The problem that was identified here was most of this process was done manually and human error and time come into play. It is vital that the data is recorded accurately, as this affects the cost estimation and all other processes that follow. Cost estimations may take a while, and the individual also now must determine how much resources will be used. The PM can immediately identify that this is a complex problem with many variables, and so the normal quality tool will not suffice, thus investigation into further tools is necessary. Now the PM knows that they should start looking into alternative solutions which could be digital twinning software.

The final three processes consist of preliminary inspection, final quality checks and dispatch. Final quality checks have been identified as a process which is not in need of improvements currently. Preliminary inspection consists of ductility tests. The PM decides that this information should be recorded using a basic quality tool, in this case a control chart, and now the PM can set certain control limits, record the results of the tests and see where most results fall. If the results fall beyond the control limit, the PM will know that something is wrong. Most of the dispatch process is outsourced, but here CRPM decides that they can record the results of the implant, i.e., how well the implant fit and what did were the problems with the implant, if any. The PM decides to use the check sheet as well as the pareto chart. The check sheet will allow the PM to see which event caused the most defects etc. The same goes for the pareto chart, with the only difference being that the pareto chart will give an indication of what caused the most failures, after which further investigations can be conducted.

Now the PM can easily identify what quality tool to use where to ensure that the problems associated with each process is solved.

To expand on the example further, when the PM decides to further investigate and has already identified that the problem is complex, he then discovers there is a need for a new tool (this whole process was outlined in Chapter 2) or software. He then meets with the business unit (his team) and discusses further requirements (done in the beginning of Chapter 3). In the case of CRPM, this would be that they want to focus on the optimisation of time and money. The summary of requirements is then compared to the five bullet points. (The summary of requirements was done in Chapter 3 where the digital twin design was done). Overall CRPM wishes to improve overall operational efficiency. The PM then checks whether the requirements include the need to duplicate processes to predict how they will perform. If yes, he will start investigating digital twinning. CRPM wants to optimise the use of time and money and maintain their desired level of quality, and the only way to do this, is to use a tool which helps one to determine how much time and money will be used for each implant (which is shown in Chapter 3), where after IT will analyse top-rated digital twinning software based on requirements and price range. There are many different types of digital twinning software.

"A digital twin is a special type of simulation model that represents a specific example of something in the present, such as a machine or a business process. It is achieved by combining current data from the subject with its simulation model." ~ AnyLogic Website

Many different types of software can be chosen to build a digital twin, such as:

- Microsoft Azure
- aPrioriDigital Manufacturing Simulation Software
- IoTIFY
- Ansys Twin Builder
- AnyLogic
- Simio

As CRPM is a relatively young company (established in 1997 as part of a research initiative), and digital twinning is a new concept, it was recommended (for the purpose of this research) that software with the lowest cost possible or no cost at all should be found. After researching the above softwares, it was decided to go with AnyLogic software. Since no funding was needed, no proposal was drawn up and the building of the digital twin could start immediately. The build of the digital twin is only a tiny part of what a proper digital twin at CRPM can be and was done to show the reader how effective it can be.

The researcher found the following advantages of digital twinning regarding TDABC: The costing simulation, which acts as a very basic digital twin, eliminates a lot of errors that can be made when using something like Excel because it is mostly automated. If this simulation is taken further, it can be made completely automatic, as it can possibly be linked to the physical process and there would be no reliance on man. The simulation would update automatically when the system updates, and the cost of each step will automatically be worked out. The simulation gives the user a better perspective into TDABC, as the user can now see how time and changes in time directly affect the amount of money coming in and going out. The user can see that it is not only the physical activity that affects the rate at which money is used but also the duration of the activity. The user can use this simulation for future planning as well, meaning that for example, if the company wants to buy another CNC machine and is not sure about the decision, the simulation can be updated, and an extra CNC machine can be added. The effects of this CNC machine in the company can then be seen, and a decision can be made based on the knowledge of how the machine will affect the product costs before the machine is bought. The more the simulation is made to be like the business, the more accurate and reliable it will become.

If the PM finds that the advantages are not enough compared to the number of hours that were invested into the digital twin, or the problem cannot be solved by a digital twin, other technologies or software are to be investigated by following the same steps until the ideal technology is found.

4.4.3 Digital twinning

The digital twin mentioned in Objective 2/Chapter 3 follows the cycle shown in Figure 4.6. The first process is the preparation process – this is where problem identification and research are conducted, approvals secured and planning and building of the digital twin executed. The next step is implementation. Once the digital twin development has started and all necessary training is completed, the basic digital twin is implemented. Finally, the last step is evaluation. Once the data is entered into the digital twin, it runs, gives results. The results can either be used or recorded. The effects of the data will be recorded and evaluated, and the new data will be entered into the digital twin and so the process continues. The more iterations there exist the more accurate results will be and the digital twin can continually adapt after each evaluation to ensure it becomes more realistic while keeping the original problem in mind the whole time.

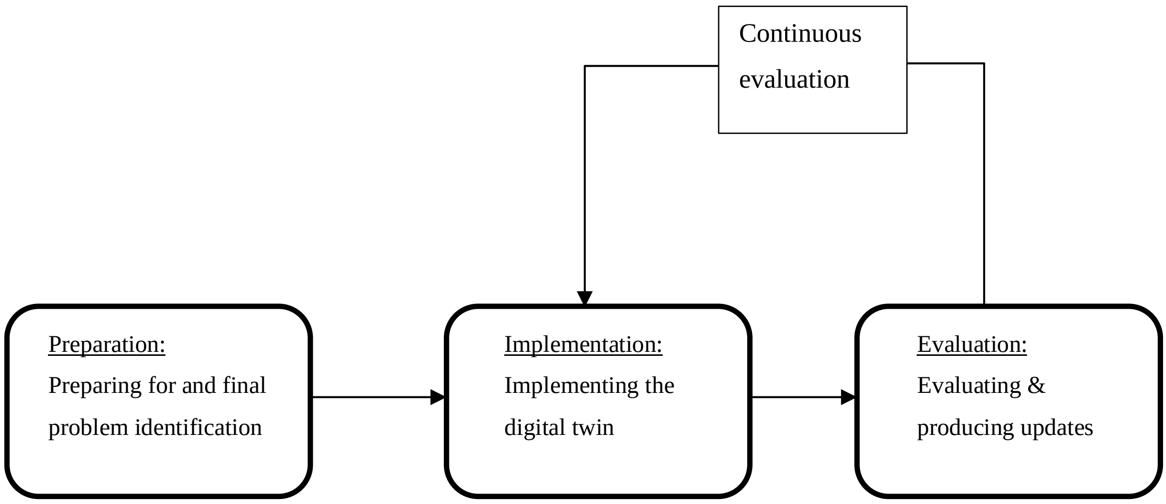


Figure 4.6: Digital twin loop

An engineer's job is to design and test products – whether cars, jet engines, tunnels, or household items – with their complete lifecycle in view. In other words, they need to ensure that the product they are designing is suitable for the purpose, can cope with wear and tear, and will respond well to the environment in which it will be used.

Examples of digital twins and how it is used to test products/processes:

1. The value of a digital twin: understanding product performance

Digital twins give businesses (CRPM) an unprecedented view into how their products perform. A digital twin can help identify potential faults, troubleshoot from afar, and ultimately improve customer satisfaction. It also helps with product differentiation, product quality, and add-on services, too. If one can see how customers are using a product after they've bought it, one can gain a wealth of insights. That means the data can be used (if warranted), to safely eliminate unwanted products, functionality, or components, saving time and money.

2. Unprecedented control over visualization, from afar

There are other advantages to a digital twin, too. One of the major ones is that digital twins afford engineers and operators a detailed, intricate view of a physical asset that might be far away. With the twin, there's no need for the engineer and the asset to be in the same room, or even the same country. Imagine engineers in Cape Town working on CRPM's process without having to physically be at CRPM. Engineers will now be able to see the effects on the process chain without having to implement anything physically and can test scenarios without having to be onsite. That means an unprecedented clarity and control over visualization.

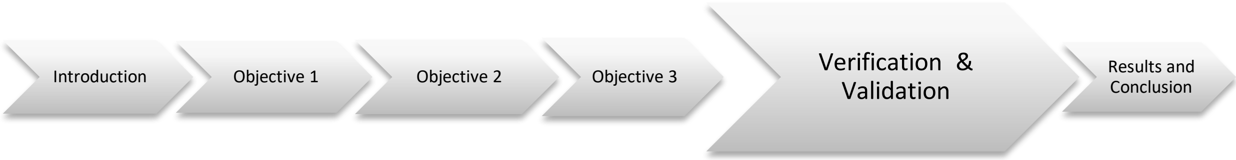
4.4.4 Digital twinning and time explained and tied together

According to an article published in The South African Journal of Industrial Engineering (SAJIE), written by the researcher of this study, digital twinning in collaboration with TDABC can be beneficial when it comes to the indication of possible bottlenecks or identifying which process may or may not be as successful as others. The article concluded that by using a digital twin in conjunction with TDABC, time and money can be saved as no processes have to be completed for identification to take place – it is known beforehand what works and what does not work. In the end, time is money, and when processes are optimised, time and consequently money is saved. The article mentions that many businesses that work in the AM industry only have a certain capacity and thus digital twinning can be used in conjunction with TDABC pre-planning to optimise the available time as much as possible. According to the article, digital twins allow businesses to see what could possibly go wrong. In return, businesses can, before faults occur, order necessary parts needed to fix these faults, thereby reducing the risk of downtime caused by broken machinery. Marketing director at EU Automation says that digital twinning models reduce development time and costs as the final construction, which follows an analysis of the simulations, improves efficiency. The article concludes that, by using a digital twin, the optimal path for a process chain can be determined and activities can resume without hesitation, even when problems occur. Thus, time that would have been spent on fixing a problem or would be lost due to having no plans in place is saved.

4.5 Objective summary

Digital twinning software provides a virtual representation or simulation of a physical asset and is used to monitor the performance of the asset in real-time. These tools are used to simulate performance, predict potential maintenance needs, and ultimately optimise the asset for peak performance. Physical assets in this case refer to business processes. Businesses embed their physical assets with sensors (processes have humans who record process data) to produce the data necessary to inform a digital twin. However, one needs to find software or a tool that suits the business needs and budget, and then it needs to be decided what to include and what to leave out. Digital twins are used for process improvement and by using multiple iterations of the process; the user will be able to determine the biggest improvement at the lowest cost. A digital twin can be used on an entire business process or on systems or sub-systems. One must determine for which processes, systems, or sub-systems it is useful and whether the use of the digital twin will be viable and sustainable. The digital twin is not necessarily the right tool for all processes in the business' process chain. This chapter proposed a decision-making tool which aids in deciding whether a digital twin is best suited for certain processes. In turn it was shown that a digital twin can aid in the optimisation of time usage in an AM business. A PM along with the business unit and IT team needs to decide whether to use a digital twin or alternatively look at other tools. The Objective reiterated that a digital twin consists of several building blocks that need to work together to achieve a fully functional digital twin. The objective proved that a digital twin can be a possible tool for time optimisation for an AM business.

5 CHAPTER 5 – VERIFICATION AND VALIDATION



In this chapter, the research questions are revisited to see whether they were answered in this research. This chapter also verifies and validates the research in this research report.

5.1 Verification and validation

Verification is defined as the testing of one’s product to determine if it meets the specifications/requirements that have been specified (did I build what I said I would), whereas validation tests how well one addressed the business needs that caused one to write those requirements. It is also called acceptance or business testing (did I build what I need).

Thus, the question remains:

Is a digital twin a possible tool to help optimise time for an AM business?

By using Table 5.1 below, the researcher can check if they met the requirements of the digital twin checklist. In this case, the researcher by completing Objectives 1-3, the researcher has met the requirements and can answer yes to the questions in Table 5.1. By using TDABC in association with a digital twin, one can schedule costs as well as times. As the event will take place in the future, the cost will only occur at that place and time. The process thus only incurs costs at the time of the action. Focussing on the optimisation of time and money can have its disadvantages as if parts are rushed, it is possible that unwanted errors can occur and thus one will need to find the optimal point between time, cost, and quality. Using the digital twin ensures that unnecessary time is not spent on post-processing due to the incorrect parameters and strategies used which results in defective parts or parts that do not meet specifications. The question, did I build what I need, can be answered with “yes”, as it is a tool that aids in the optimisation of the use of time and money. Table 5.1 acts as a checklist to ensure the digital twin achieved what was needed.

Table 5.1: Digital twin checklist

Does the digital twin…	Yes/No
…represent assets in the physical world with a digital model?	Yes, it is a representation of the AM process as well as the costing system that goes with it.
…connect with relevant time data to ensure the model mirrors reality?	Yes, users enter current data manually.
…look and feel like the real environment?	Yes, it looks like a basic version of the environment, could be improved.
Is the digital twin more than just a data model which includes relational interaction?	Yes, the digital twin can be changed, adapted continuously.

Finally, to validate the model and to get feedback concerning its applicability and suitability, our model was tested on an industry use case. We can conclude that our method can be used to help companies to identify their current capability for data utilisation, to derive areas of improvement, and to define their future strategic steps. The industry use case was the design and application of the digital twin according to the process chain at CRPM and how it operates.

The digital twin can run many times, producing different results, and can be adjusted according to real-time data. More detail can be programmed into the digital twin as well (Chapter 3). The digital twin was shown to be considered as a quality tool in Chapter 4, and quality tools are used to ensure that the quality of processes or products remain up to standard. By having a digital twin of the process, one can identify if the process is running as it should, and how it would work if data is altered. The more the digital twin is run, the more information the user will have, and patterns will start to form which will help CRPM to identify unnecessary money and time usage. The digital twin continuously evaluates the data and so continuous improvements can be made.

5.1.1 Digital twinning vs. simulations

Digital twinning is a concept, not a single product or piece of technology ~Vijay Raghunathan~

Simulations deal with pre-planned iterations. Here a certain variable e.g., variable x changes between the value of two set boundaries (i.e., between 1 and 50 with steps of 2) and outputs are monitored. Only one parameter is monitored at a time. Boundary testing is done to see how the parameter performs as it gets closer to boundaries. It is a structured approach to iteratively changing input parameters and monitor systems dynamics by observing output parameters.

Digital twins are unorganised systems that receive parameters without a structured process. Digital twin boundaries are not known or set. Digital twins are used to simulate close to boundaries in an unstructured multiple way. One of the key aspects of digital twins is that it has to be associated with an object or process that actually exists: a digital twin without a physical twin is a model. The digital twin created in the 2nd Objective does indeed have a physical twin which consists of the process conducted at CRPM followed to additive manufacture medical implants

The basic concept of the digital twin is quite new. This involves merging virtual engineering models with the physical product or equipment in an environment that allows for change and optimization of the as-designed and as-built product. Regarding the Anylogic example, the process can be updated and adjusted to allow for changes to occur. One can adjust and alter the example until the process has been optimized

When it comes to differences, there are three key differences between digital twins and simulations:

1. Digital twins have real-time simulations – digital twins are simulation engines that are focused on real-time data and interaction. The researcher's examples can be applied with real-time data to view outcomes.
2. Digital twins optimize real-world products and processes – the researchers Anylogic examples are based on the additive manufacturing process at CRPM

Digital twins enhance product or process design. The researcher's Anylogic examples focus on improving the flow of the system, optimising time and money and so enhancing process design.
Digital simulations recreate an object, process, or system however do not focus on projecting it into the future. Without this crucial feature (projecting into the future), no immense development progress can be made because companies won't be able to see what effects the new changes will have. This is what a digital twin allows in the case of the Anylogic model, it is a combination of a simulation and a basic or foundation for a future working digital twin. The Anylogic example acts as a virtual representation of the real-world process and real-time data can be entered to see the impacts on the system. The system can then be adjusted accordingly to see the impact of the new changes, and thus the process can continuously improve. In an ideal world, where computation would be instantaneous, and accuracy would be perfect, digital twins would use models derived directly from physics that took all phenomena likely to affect the quantities being measured and updated into account. For instance, a digital twin of an additive manufacturing machine would be able to simulate the thermal and mechanical processes involved in 3D printing implants using laser

sintering in real-time and update knowledge about laser wear based on real-time measurements of part temperature and shape, so that the machine maintenance could become more proactive and efficient. This can be taken further in future studies.

5.1.2 Expert opinions

Both examples are basic examples of real-life systems. Both examples can be adjusted and edited to be more accurate and precise and to look more like the real-world system. Both examples are only for explanation purposes, and to ensure that the research is valid, experts were consulted.

To validate the idea behind these examples, experts involved in all parts of this research were interviewed. An orthopaedic surgeon was interviewed as this specific surgeon works with the AM of medical implants himself and knows exactly what goes into the process and even into the processes after the manufacturing has been completed. From the medical perspective, it was seen that digital technologies improve doctors' and students' learning. Digital technologies activate another part of the brain (visual, touch, speech, etc.), which allows doctors to see procedures or problems before they happen. In this way, a doctor can focus on new problems that arise and not on the standard steps. Thus, even if the digital technologies are not a replication of the exact real-life system, they still help with learning and activate the part of the brain that solves problems. In the same way, additive manufactured preoperative models affect the brain; thus, if AM can become a more cost-effective and affordable way to supply medical implants and preoperative models, doctors could possibly be more prepared.

The second interviewee, Mr. Marius Vermeulen, is an expert in the field of building AM machines, how they work, and the processes involved. According to Mr. Vermeulen, digital twins are of utmost importance for big companies. A company can almost not be seen without some sort of simulation or digital twin as it increases in size and complexity. In his line of work, he needs some sort of way to be able to work out exactly how he came to his conclusions if a customer requests more than one AM machine and wants to know what else is needed. By using a digital twin, a customer can see possible ways they can plan the layout of their facility and how it could work when it is implemented (if this is built into the digital twin)

Mr. Johan Els, operations manager at CRPM, mentioned that the digital twin built would aid in the process development at CRPM more than product development as the process parameters can be adjusted and the outcomes viewed. He also mentioned that the digital twin will help the company to be able to plan with less uncertainty and possibly with more accuracy. According to Mr Els the digital twin can aid in logistics planning as delays in the process can be viewed before the actual process occurs.

5.1.3 **Use-case comparison**

To validate and verify the digital twin further, a case study was used to compare what was built. The Case Study is comprised of literature that was found relating to digital twins.

An article written by researchers (Resman, Protner, Simic, Herakovic, 2021), at the faculty of engineering at the University of Ljublana spoke about a five-step approach used to plan data-driven digital twins for discrete manufacturing systems. Here they suggested 5 steps that one needs to follow to plan a digital twin. The steps included identification of the manufacturing system and classifying them into four groups, namely Fabrication, Logistics, Inspection, and Storage. Step 2 includes determining the sequence of processes in the manufacturing system. Step 3 consists of determining the parameters that are necessary to build a digital model using simulation software systems; each system requires different parameters to be looked at. Step 4 consists of connecting the real/physical system to the digital model, which then gives one a digital twin by a feedback control loop. In Step 5 visualization is introduced for different parameters for decisions to be made.

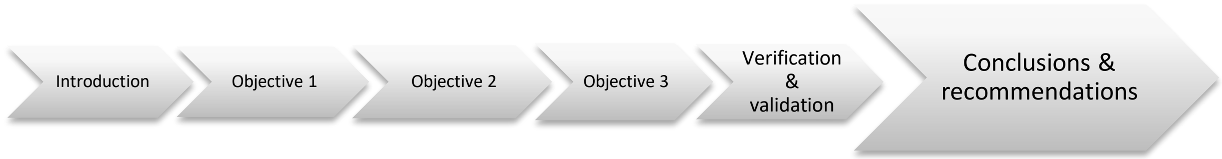
When the researcher compares these 5 steps to Objective 1-3 the following was determined: Step 1 and 2 was achieved by completing Objective 1 as the process chain was studied thoroughly and process chain diagrams, as-is vs. to-be diagrams, Ishikawa diagrams were all used to determine the flow and problem areas of the business. Step 3 and 4 was achieved in Objective 2 by determining what needs to be built and connecting what was built to the real world – by manual operation for the time being. Step 5 was achieved in Objective 2 as the outputs given by the AnyLogic examples act as visual aids for decision making. The decision-making tool also acts as an aid for giving a business the opportunity to see if they could possibly use a digital twin. An example was also proposed on how to take the digital twin further and how it can be made more custom. The steps laid out by the researcher in Objective 2 are of a similar nature to the steps proposed in the article written by Resman, Protner, Simic, and Herakovic, which indicates that a similar process is followed. This acts as validation that the correct research approach was used to develop the digital twin. The research was not based on the article and so the article reaffirms the research method that was followed.

5.1.4 **Research process**

As a part of the research process, a paper entitled “TDABC related to digital twinning in AM” was written and accepted for publication in the SAJIE. The paper confirms the use of the two tools together in order to achieve time optimisation and confirms that a digital twin is a tool that can be used in the optimisation of AM businesses. The feedback was positive confirming the acceptance of the model by the peer reviewers. Expert review is partial proof to validate the outcomes of this research.

In the literature review in Chapter 2 under the heading “Digital twinning”, the literature mentions that, due to the predictive nature of digital twinning, money and time are saved.

6 CHAPTER 6 – CONCLUSIONS AND RECOMMENDATIONS



This is the final chapter of this research document. It outlines the results obtained from the research and the findings of all three objectives. An overall conclusion and recommendations for future work are also provided, and the contribution of this research and the conclusion of Chapter 5 are described.

6.1 Contributions to practice

The intense analysis of the process chain by SWOT analysis, cause-effect diagrams, and As-Is vs. To-Be tables helped the researcher to understand the process chain more thoroughly and to identify recurring problems within the process chain. The AnyLogic examples provided insight into how powerful a digital twin can be within a business. The digital twin acts as a planning tool with which a business can prepare for any situation since predictions can be made before actual work is done. The digital twin can also aid a business in using time and money efficiently, as it allows the user to make a costing prediction within seconds and can adapt to each new implant that has to be manufactured. The researcher proposed a set of steps to create a digital twin, which can act as a guideline or a foundation for future researchers to build on. A decision-making tool for individuals/businesses with which to determine whether there is another, simpler quality tool for identifying and solving problems within their business is also proposed.

CRPM, situated at the Central University of Technology (CUT), is a research facility that prides themselves on their successes regarding AM. When speaking to Mr. Johan Els, it was evident that some improvements are needed but that both funds and time are limited. The AnyLogic examples which act as basic digital twins of the company and its costing system have shown that it is possible to make changes and plan funds and times without changing anything to the physical process chain or the physical environment of the company. The software used did not cost anything, which proves that basic digital twins can be built for next to nothing if smaller problems need to be solved. However, knowledge of the software and digital twins are required.

According to the experts who were interviewed, digital twins will have a positive effect on a business whether it is big or small. Businesses can use it as a tool to help educate employees on how the business works or can use it as a planning mechanism for future ideas or even use it as a costing system that can be automatically updated. It all depends on the goals of the business in question. Digital twins can be used to better understand how a company needs to change and what the effects of certain changes will be. Digital twins allow for plans and changes to become a reality.

6.2 Recommendations and future work

6.2.1 Recommendations

The AnyLogic examples and most of the research in this study focus on the six main processes that happen at CRPM, namely sales process, implant design, AM of the prosthesis, post-processing, final quality checks, and dispatch. To allow the digital twin to function at its best and to give CRPM the most accurate results, a more detailed digital twin – which includes the sub-systems and processes that occur within the six main processes – will need to be designed and built.

It would only be possible to classify the digital twin as 100% effective after it had been implemented at CRPM for a long time, as the digital twin makes changes as the iterations go on and adapt in real-time. It will therefore become more accurate over time as more data is collected and the digital twin adjusts accordingly.

The AnyLogic examples are based on the idea of medical AM and manufacturing companies in general. However, the parameters and parts of it will have to be altered when applying it to similar companies. This shows the power of digital twins – it is completely customizable.

It is important to focus on the critical path (longest sequence of tasks that must be completed to successfully conclude a project) and the activities (any activities that if are delayed the whole project is delayed) that make up this critical path because this will be the activities that have the biggest effect on the process or business. For example, the user can look at both the digital twin and powder management, but then the ordering of powdering, measuring of the correct batches for each job, stock intake, etc. would also have to be included in the digital twin, which makes the process complex. By focusing on what is important (SOPs), the user can have a quality management system that can address these SOPs. It is important to make sure the powder is in stock though. It must be in place for the critical path to function, otherwise, the critical path will be delayed, which is counterintuitive to TDABC.

6.2.2 Future work

The decision-making model that was produced can be further developed and expanded into a chatbox, which can be an automatic system that indicates which tool to use for the problem at hand, within a few minutes. The AnyLogic examples can be expanded on, and more complexity can be added to ensure more accurate results.

CRPM should investigate the use of other digital twinning software, and, if they are serious about implementation, they should investigate a professional vendor who can run, build and implement the digital twin for them. In this way, they can ensure the most accurate and true-to-life results. CRPM should also allow more details and include the sub-processes and -systems to be built into the digital twin to ensure the most accurate results.

Building a digital twin of the actual printing process can be an extremely effective tool for CRPM to be able to predict maintenance times and predict possible machine downtimes. If the company can have a virtual replica of the actual printing process (i.e., be able to see how much powder each print will take, how long it will take, let the print run virtually, and see the effects) one will be able to plan around when the machine will be busy, possible down/idle times and even run defective parts to see how to plan for these various situations. A digital twin of this process will be quite complex to build but is possible and can have various advantages.

6.3 Conclusion

This research acts as an investigation into and basis for building the foundation of a digital twin for a business. It shows and explains how a company such as CRPM can use digital twinning to optimise their business. Industrial engineering focuses on the optimisation of among others time, and this research adds to industrial engineering’s base knowledge about time optimisation through digital twinning. Digital twinning can aid in planning, implementing, and decision-making with regards to changes in the business. With the aid of the digital twin, employees could be taught about the layout of the business and the processes and sub-processes that take place. According to experts, some sort of digital twin is essential to a business and can only be beneficial. Digital twins can be linked to costing systems, and as seen in Chapter 3, it can assist in the use of TDABC. The business (CRPM or businesses in general) must decide for which processes a digital twin will be suitable or valuable. Tools already exist for multiple high-volume processes. However, tools that work for high-volume processes will not necessarily work for high-customisation processes. For CRPM, a digital twin will be able to aid in the optimisation of time usage. At this stage, it is impossible to predict if it will be useful for the entire business, but it has been proven that the digital twin acts as a possible tool to help with time optimisation. The research helps one to realise just how complicated the design and execution of a digital twin can become. It is important to not only focus on the digital twin but also on the development of the building blocks necessary for the digital twin to function. For digital twinning it is essential to consider all the separate parts, meaning that the whole process or business should be considered. At the end of the day, the decision is made by the human, e.g., the management. A digital twin is therefore only a decision-making and optimisation tool, while the ultimate decision still lies with management. For this research, technical feasibility was not the goal; however, commercial feasibility was, and for this, digital twinning can act as a planning and decision-making tool. Objective 1 was achieved by the intense investigation of the process chain wherein areas of improvement were identified within CRPM. A possible solution – a digital twin – was identified to bridge the gap. In Objective 2 steps were determined to develop a digital twin and the process was started and basic digital twins were developed. In Objective 3 the basic digital twins were integrated for business by developing a decision-making tool that can be used by any business to determine if digital twinning could be an option for their business. Continuous evaluation was implemented throughout the entire process.

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APPENDIX A: TRANSCRIPT OF EXPERTS

Experts were consulted to guide the student along the research process and to validate the research.

#	Expert	Job description/expertise	Reason for interest
JE	Johan Els	Operations manager at CRPM	Industry partner
RV	Dr Rudolph Venter	Orthopaedic Surgeon	Specialises in research of 3D printing medical implants and physically implants the printed material into patients
MV	Marius Vermeulen	Owner of Aditiv.Solutions Previously worked at Aerosuit	Company builds 3D printing machines for customers. Worked at a company called Aerosuit
FD	Francois du Randt	Technician at VUT and PhD student	Works with set-up and maintenance of machines. Research field is related to 3D printing

TRANSCRIPT OF INTERVIEW WITH JOHAN ELS

How do you think a digital twin will affect the following:

Quality management:

JE: A digital twin might enable you to plan with more certainty and accuracy.

Product redesign:

JE: If a digital twin could for instance identify why a particular design could fail during printing, you might be able to redesign it prior to actually printing it in order to avoid a failed print.

System planning/virtual start-up:

JE: n/a

Logistics planning:

JE: A digital twin could potentially identify a process step that could fail and cause delays which can be addressed in order to avoid products failing.

Product development:

JE: I have a feeling that a digital twin might be a lot more relevant when it comes to process development. With product development, it will be hard to replace a physical prototype in hand to get a real feel for a product. FEA and CFD analysis during product development can already identify problems during product development, but you need a physical model in hand to get a good idea in terms of functionality and ergonomics.

What is the main problem or re-occurring problem you are currently facing within your process chain?

JE: Our biggest challenge is lost time due to outsourced processes. If any process during the process chain goes wrong, it has a huge time delay on the delivery date of the product and in many cases where state hospitals are involved, you are unable to postpone a procedure date due to the limited theatre time available.

TRANSCRIPT OF INTERVIEW WITH DR RUDOLPH VENTER

Why is AM of medical implants or preoperative models important to you as a surgeon?

RV: The doctor feels like he has performed the operation before or as if he has had a practise session. In turn, it boosts the doctor's confidence as he is not seeing the operation for the first time in the theatre. The old way of planning was visual and the execution was haptic, which means touch, thus there was a gap between the two and a link is necessary to convert from the one to the other. When you use something like preoperative models, it is like using Google street view, you can actually see how the place/bone will look like and you become much more familiar with the terrain. In turn, the actual haptic experience is already encoded in your brain and so there will be a smaller cognitive load. Lower cognitive load means that there is enough attention that can be given to other things that can go wrong i.e. anaesthesia, bleeding instead of the routine operation. Some surgeons play the same music every time that they operate; this allows the subconscious to remember each time that this specific music plays what has to happen. Thus the team work more efficiently. Most research is about blood loss and how to get patients out of the hospital quicker; however, there is no control with exceptional cases. Thus there exists no evidence for exceptional cases. Research should show that the more prepared the surgeon is, the more awake he will be, which will lead to less mistakes. This is where AM comes into play.

As a doctor researching the 3D printing area, do you believe a simulation/digital twin of the AM process could be useful?

RV: If it will help to manage your team, then definitely. Or if it helps with embodied learning, in other words if you can use a digital twin to feel, see, or experience the process beforehand. Different technologies can be advantageous to people in different ways. For example, planning. If you can use digital twinning to adjust the parameters of the theatre like making the theatre busier, having more people moving around etc., then you can test how certain people will react under different conditions. We use virtual reality to practise knee replacements.

What would you say would be the most important characteristic a digital twin would need for you to be able to benefit from it?

RV: Making sure that the user is exposed to the parameters that he will experience before the surgery and before he has been exposed to the patient. It will definitely differ for a more experienced doctor vs a new and young doctor.

TRANSCRIPT OF INTERVIEW WITH MARIUS VERMEULEN

In your opinion, are simulations a valid way to predict how processes could possibly work under certain circumstances?

MV: This is a difficult question. I guess it depends on the data that is available and how in detail the simulation is built. For us, our machines are already expensive and they print very slowly, so optimising machine time is of extreme importance. Eighty percent of our costs are hardware costs inside of the process, and most of all, time. If a digital twin can help optimise our machine time, it definitely is a tool option to consider

Have you used any form of a digital twin in your working environment?

MV: None as of yet.

If so, how has it benefited you or your work?

If not, do you believe that a digital twin or a simulation of sorts could be beneficial to your business?

MV: Yes, I believe it will be beneficial. Especially when it comes to client interaction. For me, this would be the first step of my business that I will take to the digital level. Quoting specifically has become a huge cost driver and consumes a lot of the time that is available; if it would be possible to make this digital by using some sort of formula, it would be great.

If a customer asks me he wants 10 machines and also wants to know what he would need besides the AM machines, I will definitely resort to using simulations. Now the question becomes: How you optimise your employees and resources, using one machine vs using three machines, which add more complexity to the situation? Using a simulation would be a great way to test what will be needed and how optimisation might be achieved. I definitely see simulations as tools that add value to the company; it will definitely help with resource planning and how to get facilities going. It is important to know how many people and resources will be needed for pre- and post-processing as the number of machines change as now it is not an obvious question anymore. Simulations can possibly help to identify this.

Would you, in the business that you are in now, move towards using digital twins?

MV: Yes and no. “No” because currently we only manufacture AM machines and are merely the middle man in the process and don’t have the database for it. “Yes” because if it can act as a tool or building blocks exist – i.e. you do not have to build the model from scratch and models actually exist which you can build on – I will definitely use it. It also becomes more cost and time effective then. A digital twin will be beneficial for set-up.

Do you think it will be cost-effective? (Keep in mind licence costs and the possible effect of less people needed to work for you.)

MV: I think it all depends on the scale of the business. If you have a small company only using one or two AM machines it is possible to keep track everything using Excel. However as the scale of your business increases, so the complexity of the process chain and business also increases. I used to work for Aerosuit, and in a company like this, I would say it is almost impossible to go without some sort of simulation of the company.

TRANSCRIPTS OF INTERVIEWS FOR OBJECTIVE 1:

Marius Vermeulen (MV)

Most important factor (in your opinion) between time, cost and quality? Why?

MV: It depends heavily on the application industry. AM lends itself well towards high-value, low-volume industries. For many of these industries (such as Aerospace and medical), quality is the driving factor. However, to make the technology viable for other industries, cost plays an important role and it is to some extent very closely related to time. By way of example, the cost of AM parts is driven by the cost of the machines, as the machine cost drives the hourly rate of the machine. Ergo, to manufacture parts at a lower cost, you need to focus on speed.

Biggest problem you have experienced in the AM business?

MV: Getting companies to use AM correctly. In my experience, companies are often either ignorant of where AM can add value to their businesses, or they try to use AM in areas where other processes are more efficient. AM is a new tool in companies' "toolbox" and they need to learn when to use the new tool, and when to use the trusty old screwdriver.

If you could alter one thing about the AM process, what would it be (big or small) and why?

MV: Increase manufacturing speed.

- **Biggest risk you have identified in the following AM processes:**
- **Sourcing of raw materials and raw materials used in general?**

  MV: Safety risk in handling and storage of reactive metals (titanium and aluminium).

- Design process (medical implants, any object to be printed)?

  MV: Handling of large data files. STL file formats can be huge when handling complex geometries. This causes issues with simulation and prediction software.

- **Manufacturing process (actual print, machine set-up etc.)?**

  MV: Part distortion during the build process.

- **Material handling (removing supports etc.)?**

  MV: Maintaining integrity and traceability of powder.

- **Do you believe sufficient planning tools exist in order to assist the AM process? (e.g. pre-process planning tools, training etc.)**

MV: No, but the planning tools have evolved drastically over the last 3–5 years and still is.

Johan Els (JE)

Most important factor (in your opinion) between time, cost and quality? Why?

JE: To be competitive as an AM service provider, in my opinion, you must have a balance between production times, part cost and part quality. There is no use having a fast process resulting in poor quality or having a really good quality component that does not meet the client's deadline.

Biggest problem you have experienced in the AM business?

JE: High equipment and material prices due to forex fluctuations as well as a delay in getting material or spares from OEM's on short notice.

If you could alter one thing about the AM process, what would it be (big or small) and why?

JE: Improved surface quality to reduce post-processing.

Biggest risk you have identified in the following AM processes:

Sourcing of raw materials and raw materials used in general?

JE: Refer to point 2 above.

Design process (medical implants, any object to be printed)?

JE: High cost of certified software.

Manufacturing process (actual print, machine set-up etc.)?

JE: Process monitoring to ensure consistent part quality.

Material handling (removing supports etc.)?

JE: Possible damage to small and intricate parts during support removal due to excessive force used.

Do you believe sufficient planning tools exist in order to assist the AM process? (e.g. pre-process planning tools, training etc.)

JE: Various fantastic tools are available but at a very high cost to acquire for limited use and small scale production. An ideal would be to have access to such software on a case by case basis on a token system for example.

Francois du Randt (FdR):

Most important factor (in your opinion) between time, cost and quality? Why?

FdR: In my opinion, quality is the most important factor when relating to AM. If the quality is not present, then the cost and time factors are irrelevant. One can always look at time and costs at a later stage to see if you can drive them down. It does not help your product is quick to manufacture as well as cheap but it is, for lack of a better word, useless.

Biggest problem you have experienced in the additive manufacturing business?

FdR: Original equipment manufacturers. When you have a problem with a machine, you have to speak to them, their first language is not English, and it becomes a tedious process. They also tend to limit their machines to processes and materials that only they can work with. Meaning if they are not working, you cannot work. They need to provide you with the materials and knowledge that you need.

If you could alter one thing about the AM process, what would it be (big or small) and why?

FdR: I would say it is important to broaden the manufacturing of the actual machines, or open up the process; keeping the ideas open-sourced and not only associated to one person. I believe it is important that the AM industry becomes more transparent and that it is not only about money and worrying about oneself. If people would start collaborating on ideas, the AM industry would have been much further along. However, now patents exist and this causes technology to stagnate. Thus, the propriety business model is causing the technology to stagnate. How the machines work and the company's business models are becoming big problems. They need to allow for improvements and innovation to take place outside of their company. It has happened to me that when we worked with companies, they did not like the clauses that were added in the research contract and the company ended up just leaving. Some companies have, however, started to patent only the improvements that they make and not the entire process.

Biggest risk you have identified in the following AM processes:

Sourcing of raw materials and raw materials used in general?

FdR: In a South African context: we do not have the capability to manufacture raw materials on our own. Thus, materials need to be imported. This whole process becomes quite expensive and AM thus is not a cheap venture in SA. SA has found a quarry that has sand that they can use, and research has been started in the metal industry. (Pelendaba has started building a plant). Polymers, however, are very expensive and there is quite a waiting time (6 weeks), so either you have to work in a large lead time to ensure you will be able to wait that time if you do not have enough resources or you have to have a lot of material on hand. Sourcing of these polymers is also generally a difficult process.

Design process (medical implants, any object to be printed)?

FdR: Not my field.

Manufacturing process (actual print, machine set-up etc.)?

FdR: Again, in a South African context, factors have to be taken into account which other countries do not necessarily have such as: power outages or shortages, even if you have generators etc., some things like a compressor, you cannot run on it, thus you lose air pressure and the build stops. When it comes to machine set-up, it depends solely on the operator. Even though we have SOPs in place, it is difficult to enforce these SOPs. Unfortunately there are not consequences for your actions (which is not the case everywhere in SA). It all depends on the mood of the employees on the day, planning becomes quite useless. By us, Malan has to go check even after the operator has set up the machine, just to ensure that it has been done correctly. If the job fails, it is a few thousand rands that is wasted and so much time. To do everything from scratch becomes impossible, some prints take as long as 27 hours. By us, we also do not want the operators to remove some of the prints, as, if it is not remove correctly, it gets damaged. Engineers have to do this job as well because the operators are not trusted. CUT, however, is ISO accredited and this will not happen by them because they would lose accreditation.

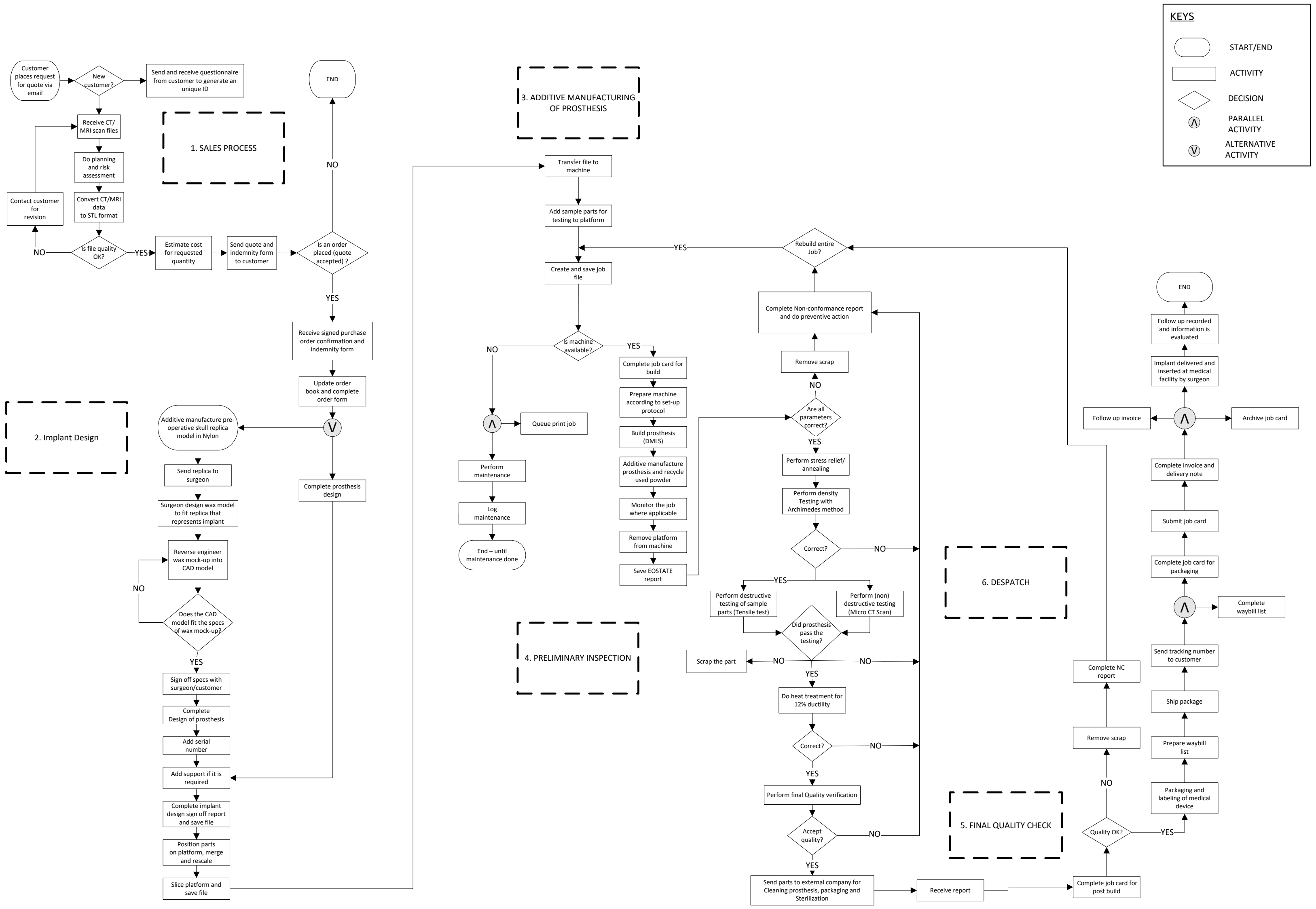
Material handling (removing supports etc.)?

FdR: Operators really need to be very focused on what they are busy with. They need to know what they are doing from beginning to end. A lot can go wrong.

Do you believe sufficient planning tools exist in order to assist the AM process? (e.g. pre-process planning tools, training etc.)

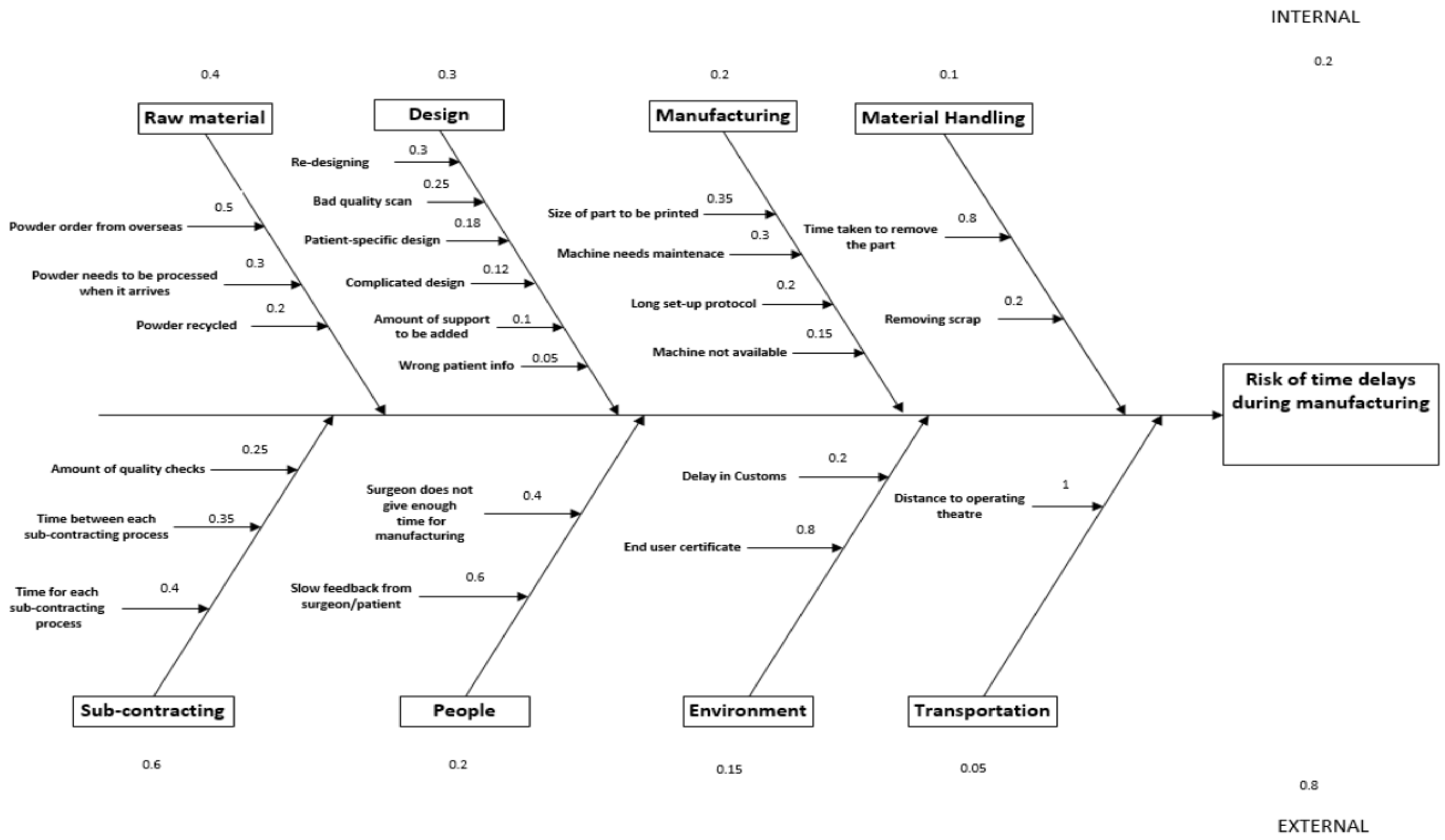
FdR: There definitely is a place for planning tools. We have been trying to do build planning for a while now. It is important to be able to plan which jobs have to be done first etc., to plan which orders are done when and will take how long. It is important to plan how the process will flow, what will be done and which job is done first (determining the importance or most optimal scheduling). If a job fails, you need to be able to have a plan in place on how or when to reschedule or if you would need to reprint the whole job or only a partial part. Every AM company has their own way of doing things and what planning tools would work for them; currently we are working with Excel, which is not ideal. I am not always sure if planning tools cater for AM processes specifically but more for general or normal engineering works. AM has only a few processes that needs planning, whereas milling machines etc. have much more details that can be pre-planned. Thus, these planning tools are not really suitable for AM.

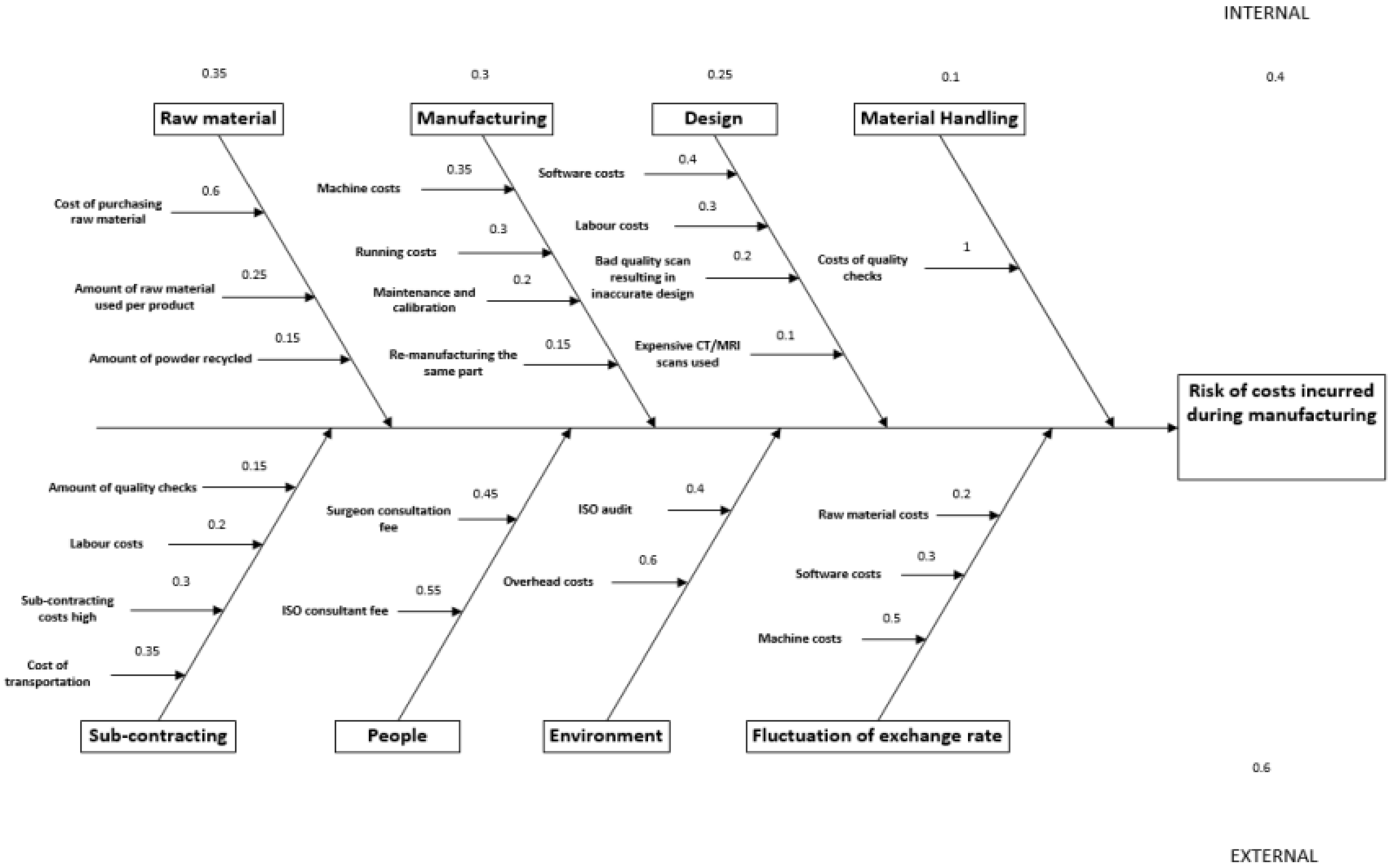
APPENDIX B: PROCESS CHAIN AT CRPM



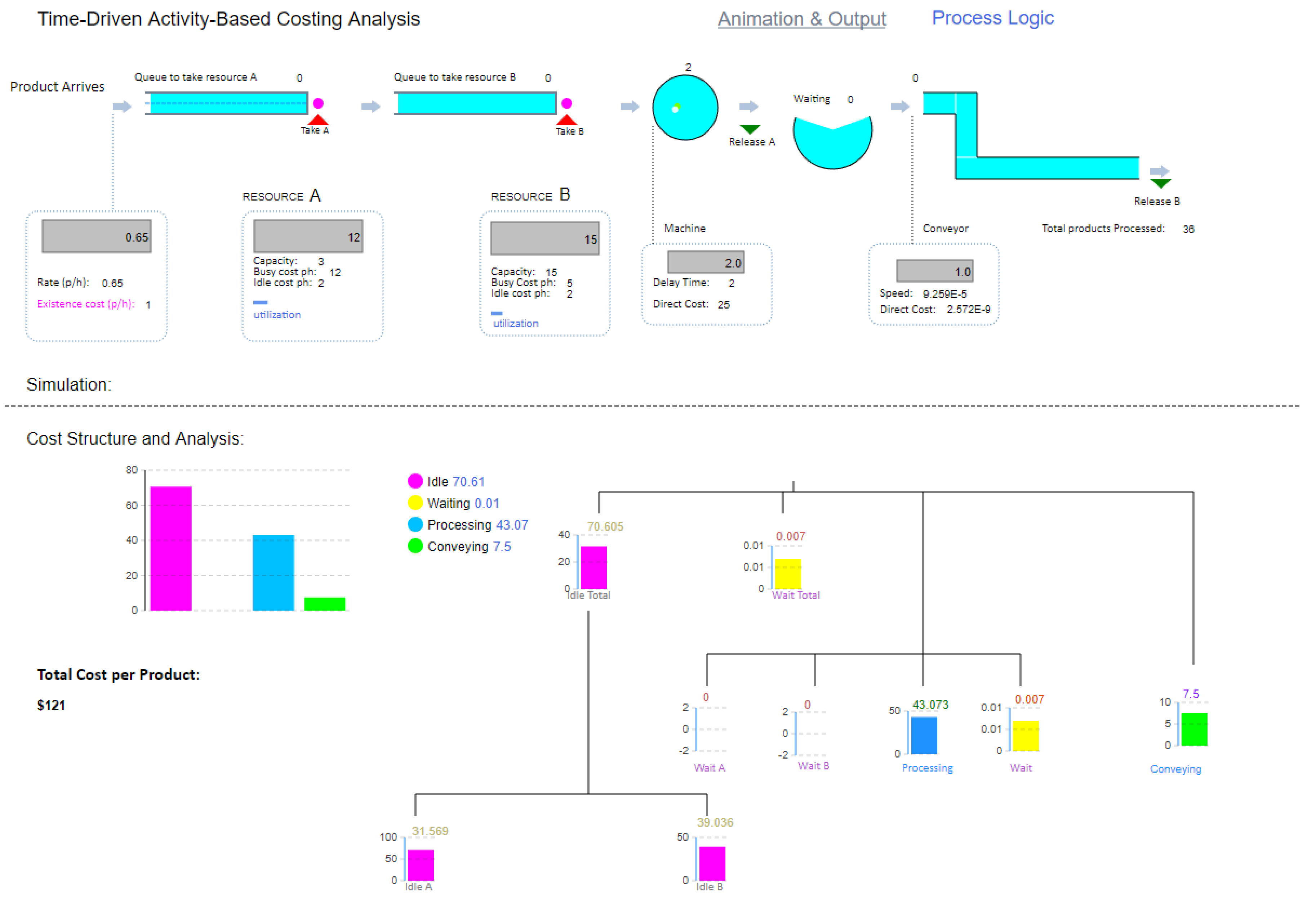
APPENDIX C: ISHIKAWA DIAGRAMS

Ishikawa diagrams were needed to identify problem areas at CRPM.

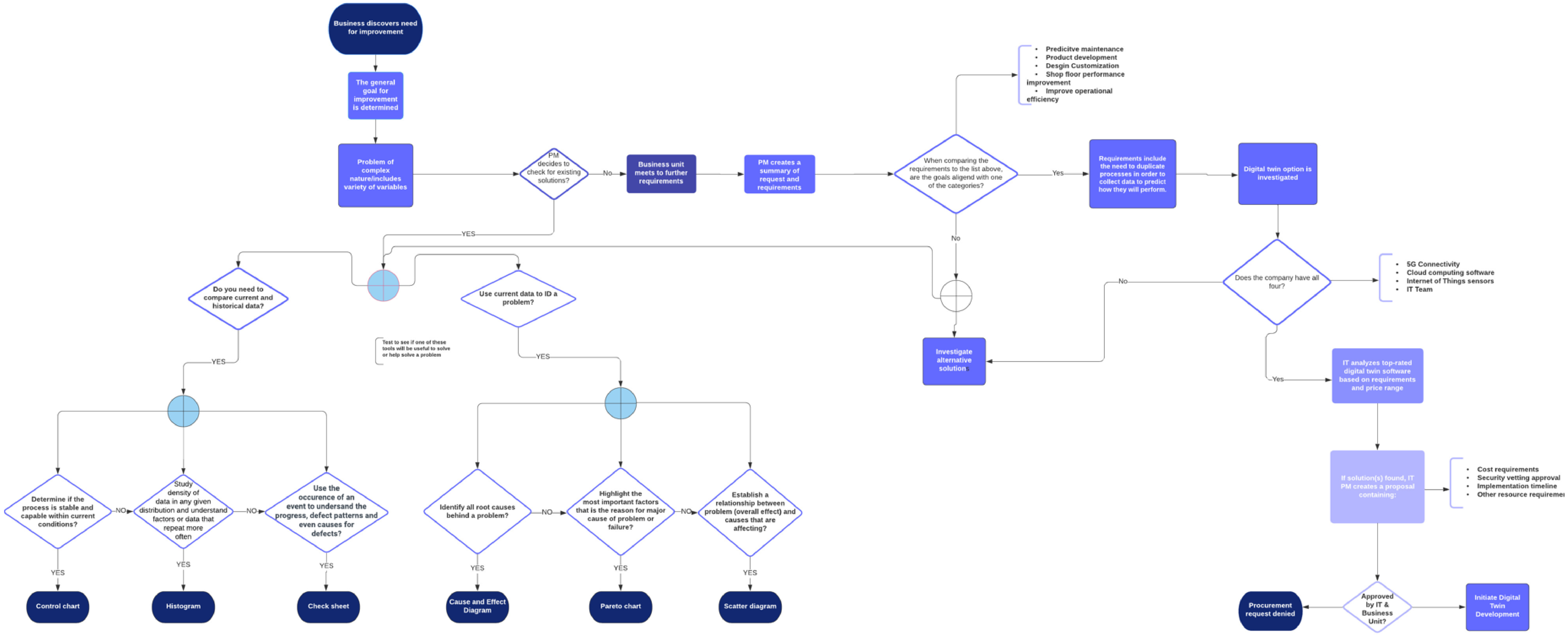



INTERNAL
0.4
0.35
Raw material
0.3
Manufacturing
0.25
Design
0.1
Material Handling
Cost of purchasing raw material
0.6
Amount of raw material used per product
0.25
Amount of powder recycled
0.15
Machine costs
0.35
Running costs
0.3
Maintenance and calibration
0.2
Re-manufacturing the same part
0.15
Software costs
0.4
Labour costs
0.3
Bad quality scan resulting in inaccurate design
0.2
Expensive CT/MRI scans used
0.1
Costs of quality checks
1
Risk of costs incurred during manufacturing
Amount of quality checks
0.15
Labour costs
0.2
Sub-contracting costs high
0.3
Cost of transportation
0.35
Surgeon consultation fee
0.45
ISO consultant fee
0.55
ISO audit
0.4
Overhead costs
0.6
Raw material costs
0.2
Software costs
0.3
Machine costs
0.5
Sub-contracting
People
Environment
Fluctuation of exchange rate
0.6
EXTERNAL

APPENDIX D: SIMULATION DIAGRAMS



APPENDIX E: DECISION-MAKING TOOL



APPENDIX F: ISHIKAWA RISK CALCULATIONS (ILIE & CIOCOIU, 2010) & (BEZUIDENHOUT, 2016)

The Ishikawa diagrams were used to identify problem areas in the process chain at CRPM. Appendix F is used to show how these calculations were done.

The total risk involved is the risk of producing main causes; therefore, it represents the weighted sum of the main causes for each problem. In this study, three problems influence one another. Each risk-formulated problem, R_i, represents the weighted sum of the risks distributed on the internal-side, RI_i, and the external side, RE_i.

The conditioning formula names that were used to calculate the risks are summarised in Table 9.

TableF.1: Summary of formulas

Formula names	Conditioning formulas
Risk of secondary causes	$\boldsymbol{R}_r\boldsymbol{I}_{iu}$, and $\boldsymbol{R}_r\boldsymbol{E}_{iu}$
Risk of main causes	$\boldsymbol{R}_r\boldsymbol{I}_i$ and $\boldsymbol{R}_r\boldsymbol{E}_i$
Risk of internal and external categories	$\boldsymbol{R}_r\boldsymbol{I}$ and $\boldsymbol{R}_r\boldsymbol{E}$
Total risk	$\boldsymbol{R}_r$

The steps in using the formula for calculating each risk are explained by the following steps:

Step 1: Determine the risks of the secondary causes - $\boldsymbol{R}_r\boldsymbol{I}_{iu}$, $\boldsymbol{R}_r\boldsymbol{E}_{iu}$

Do this by formalising the risk (R) according to the probability and impact of each secondary cause. The probability is the likelihood of the secondary cause effecting or happening. The impact is the amount of damage or the number of consequences the specified secondary cause might cause when it occurs. The probability and the impact are written as a percentage. The risk(R) of each secondary cause is then equal to the product of the probability (P) and the impact (I) of each cause.

Which yields Equation 1:

Equation 1: Risk size of secondary causes (Ilie & Ciocoiu, 2010) $R = P * I$

The CRPM helped to determine probabilities and the impact of each secondary cause through knowledge of day-to-day operations and similar events occurring at the CRPM. A table with all the probability and impact values that are used to calculate the risk, is in Appendix F. These values are subject to change due to varying factors having different effects on the operations at the CRPM. The Ishikawa model that was designed and the risk analysis are therefore dynamic.

Step 2: Determine the main risks - $R_r I_i$, $R_r E_i$

The risk of each main cause is calculated by summing the weighted risks of the secondary causes that influence the main cause, as shown by Equation 2 and 3.

Equation 2: Size of risk of internal main causes $R_r I_i = \sum P_r I_{iu} * R_r I_{iu}\ i, (3.2) \sum i, P_r I_{iu} = 1$

Equation 3: Size of risk of external main causes $(R_r E_i = \sum P_r E_{iu} * R_r E_{iu}\ i, (3.4) \sum i, P_r E_{iu} = 1$

Where $R_r I_{iu}$ and $R_r E_{iu}$ represent the risk of the secondary causes on the internal and external side respectively.

Step 3: Determine each category (internal and external) risks - $R_r I$, $R_r E$

Each category of risk is a weighted sum of the main causes of the risks distributed to the left or to the right side, as shown by Equation 4 and 5.

Equation 4: Size of internal risk $R_r I = \sum P_r I_i * R_r I_i\ i{=}1\ (3.6) \sum P_r I = 1\ n\ i{=}1$

Equation 5: Size of external risk $R_r E = \sum P_r E_i * R_r E_i\ n\ i{=}1\ (3.8) \sum P_r E = 1\ n\ i{=}1$

Where RI_i and RE_i are the main causes on the internal and external side respectively, r = Q, T, C.

Step 4: Determine the total risk of each problem - R_r

The total risk of each problem is calculated by using Equation 6.

Equation 6: Size of total risk $R_r = (P_rI \ x\ R_rI) + (P_rE \ x\ R_rE)$***, where P = weight*** $P_rI + P_rE = 1$

Process Code	Description	UOM	Process Type	Currency	Price	Converted Price to ZAR	Sensitivity	What-if Price	Error	Product Cost	What-if cost
MAX101	Maxillary Frame	Units	Manufactured	ZAR						R 67 185.00	R 69 885.00
IP01	Pre-operative model	Units	Manufactured	ZAR						R 37 480.00	R 40 480.00
IP02	Manufacture pre-operative model	Units	Manufactured	ZAR						R 34 000.00	R 37 000.00
IP03	Manufacture implant	Units	Manufactured	ZAR						R 32 600.00	R 35 300.00
RM01	Ti6AI4V powder	kg	Bought-In	EUR	200.00	R 3 600.00	10.00%	R 3 960.00		R 3 600.00	R 3 960.00
ASS01	EOS M280 DMLS Machine	Units	Bought-In	EUR	400000.00	R 7 200 000.00	8.00%	R 7 776 000.00		R 7 200 000.00	R 7 776 000.00
ASS02	EOS P385 Machine	Units	Bought-In	EUR	400000.00	R 7 200 000.00	0.00%	R 7 200 000.00		R 7 200 000.00	R 7 200 000.00
RM02	PA 2200 polymide material	kg	Bought-In	ZAR	1000.00	R 1 000.00	10.00%	R 1 100.00		R 1 000.00	R 1 100.00
LB02	Doctor's Consultation Rate	Hours	Design	ZAR	500.00	R 500.00	0.00%	R 500.00		R 500.00	R 500.00
LB03	Software	Hours	Design	EUR	15000.00	R 270 000.00	0.00%	R 270 000.00		R 270 000.00	R 270 000.00
LB04	Review design internally	Units	Design	ZAR	1000.00	R 1 000.00	0.00%	R 1 000.00		R 1 000.00	R 1 000.00
LB05	Review design with doctor	Units	Design	ZAR	1500.00	R 1 500.00	0.00%	R 1 500.00		R 1 500.00	R 1 500.00
LB06	Review CT Scan report	Units	Design	ZAR	1000.00	R 1 000.00	0.00%	R 1 000.00		R 1 000.00	R 1 000.00
LB07	Evaluate CT/ MRI data	Hours	Design	ZAR	480.00	R 480.00	0.00%	R 480.00		R 480.00	R 480.00
LB08	Translate data to STL format	Units	Design	ZAR	1500.00	R 1 500.00	0.00%	R 1 500.00		R 1 500.00	R 1 500.00
LB09	Reverse engineer frame	Hours	Design	ZAR	1425.00	R 1 425.00	0.00%	R 1 425.00		R 1 425.00	R 1 425.00
LB010	Design rate	Hours	Design	ZAR	480.00	R 480.00	0.00%	R 480.00		R 480.00	R 480.00
LB011	Design changes after review	Hours	Design	ZAR	480.00	R 480.00	0.00%	R 480.00		R 480.00	R 480.00
LB012	Cleaning	Units	Quality	ZAR	500.00	R 500.00	0.00%	R 500.00		R 500.00	R 500.00
LB013	Stress Relieving	Units	Quality	ZAR	1500.00	R 1 500.00	0.00%	R 1 500.00		R 1 500.00	R 1 500.00
LB014	Cut implant from base	Hours	Quality	ZAR	150.00	R 150.00	0.00%	R 150.00		R 150.00	R 150.00
LB015	Remove support material from implant	Hours	Quality	ZAR	200.00	R 200.00	0.00%	R 200.00		R 200.00	R 200.00
OS01	Initial polishing	Hours	Quality	ZAR	500.00	R 500.00	0.00%	R 500.00		R 500.00	R 500.00
OS02	Heat treatment at CSIR	Units	Quality	ZAR	6000.00	R 6 000.00	0.00%	R 6 000.00		R 6 000.00	R 6 000.00
OS03	Final polishing	Hours	Quality	ZAR	500.00	R 500.00	0.00%	R 500.00		R 500.00	R 500.00
OS04	Sterilization	Units	Quality	ZAR	500.00	R 500.00	0.00%	R 500.00		R 500.00	R 500.00
LB016	Visual Inspection	Hours	Quality	ZAR	150.00	R 150.00	0.00%	R 150.00		R 150.00	R 150.00
LB017	CT Scan for defects	Units	Quality	ZAR	3000.00	R 3 000.00	0.00%	R 3 000.00		R 3 000.00	R 3 000.00
LB018	Translate STL data for FEA	Units	Quality	ZAR	1500.00	R 1 500.00	0.00%	R 1 500.00		R 1 500.00	R 1 500.00
LB019	FEA analysis	Units	Quality	ZAR	3000.00	R 3 000.00	0.00%	R 3 000.00		R 3 000.00	R 3 000.00
TR01	Transport to doctor	Units	Transport	ZAR	350.00	R 350.00	0.00%	R 350.00		R 350.00	R 350.00
TR02	Doctor sends model back	Units	Transport	ZAR	350.00	R 350.00	0.00%	R 350.00		R 350.00	R 350.00
TR03	Send new design for approval to doctor	Hours	Transport	ZAR	480.00	R 480.00	0.00%	R 480.00		R 480.00	R 480.00
TR04	Ship implant to CSIR	Units	Transport	ZAR	700.00	R 700.00	0.00%	R 700.00		R 700.00	R 700.00
TR05	Ship implant to Stellenbosch	Units	Transport	ZAR	700.00	R 700.00	0.00%	R 700.00		R 700.00	R 700.00
TR06	Ship implant for Sterilization	Units	Transport	ZAR	700.00	R 700.00	0.00%	R 700.00		R 700.00	R 700.00
LB020	Maintenace (per year)	Units	Inspection	EUR	12000.00	R 216 000.00	0.00%	R 216 000.00		R 216 000.00	R 216 000.00
LB021	ISO audit (per visit)	Units	Inspection	ZAR	250000.00	R 250 000.00	0.00%	R 250 000.00		R 250 000.00	R 250 000.00
LB022	EOS M280 DMLS Machine running cost	Hours	Manufacturing	ZAR	350.00	R 350.00	0.00%	R 350.00		R 350.00	R 350.00
LB023	EOS P385 Machine running cost	Hours	Manufacturing	ZAR	250.00	R 250.00	0.00%	R 250.00		R 250.00	R 250.00

Number	Name		Code		Weights of Sec. Causes	Control	Weights of Main Causes	Control	Probability (P)	Impact (I)	Risk (R)		
	Main Causes	Secondary Causes	Main Causes	Sec. Causes									
	COSTS												
1	Raw Material		CI_1			1	0.35	1					
1.1		Cost of purchasing raw material		CI_{11}	0.6				3	3	0.6	High Risk	Unacceptable
1.2		Amount of raw material purchased		CI_{12}	0.25				3	2	0.5	Low Risk	Unacceptable
1.3		Amount of powder recycled		CI_{13}	0.15				2	2	0.4	Low Risk	Unacceptable
2	Manufacturing		CI_2			1	0.3	1					
2.1		Machine costs		CI_{21}	0.35				3	4	0.7	Maximum Risk	Unacceptable
2.2		Running costs		CI_{22}	0.3				3	3	0.6	High Risk	Unacceptable
2.3		Maintenance and calibration		CI_{23}	0.2				3	3	0.6	High Risk	Unacceptable
2.4		Re-manufacturing the same part		CI_{24}	0.15				1	3	0.4	High Risk	Unacceptable
3	Design		CI_3			1	0.25	1					
3.1		Software costs		CI_{31}	0.4				3	3	0.6	High Risk	Unacceptable
3.2		Labour costs		CI_{32}	0.3				3	3	0.6	High Risk	Unacceptable
3.3		Bad quality scan resulting in inaccurate design		CI_{33}	0.2				3	4	0.7	Maximum Risk	Unacceptable
3.4		Expensive CT/MRI scans used		CI_{34}	0.1				3	2	0.5	Low Risk	Unacceptable
4	Material Handling		CI_4			1	0.1	1					
4.1		Cost of quality checks		CI_{41}	1				4	3	0.7	High Risk	Unacceptable
5	Sub-contracting		CE_1			1	0.35	1					
5.1		Cost of transportation		CE_{11}	0.35				2	3	0.5	High Risk	Unacceptable
5.2		Sub-contracting costs high		CE_{12}	0.3				3	3	0.6	High Risk	Unacceptable
5.4		Labour costs		CE_{14}	0.2				3	3	0.6	High Risk	Unacceptable
5.5		Amount of quality checks		CE_{15}	0.15				3	2	0.5	Low Risk	Unacceptable
6	People		CE_2			1	0.3	1					
6.1		ISO consultation		CE_{21}	0.55				2	3	0.5	High Risk	Unacceptable
6.2		Surgeon consultation		CE_{22}	0.45				2	3	0.5	High Risk	Unacceptable
7	Environment		CE_3			1	0.25	1					
7.1		Overhead costs		CE_{31}	0.6				3	3	0.6	High Risk	Unacceptable
7.2		ISO audit		CE_{32}	0.4				4	4	0.8	Maximum Risk	Unacceptable
8	Fluctuation in exchange rate		CE_4			1	0.1	1					
8.1		Machine costs		CE_{41}	0.5				4	4	0.8	Maximum Risk	Unacceptable
8.2		Software costs		CE_{42}	0.3				4	5	0.9	Maximum Risk	Unacceptable
8.3		Raw material costs		CE_{43}	0.2				4	4	0.8	Maximum Risk	Unacceptable

Impact	Probability	Risks Magnitude	Risk Acceptability	Proposed Action
5	4-5	Maximum Risk	Unacceptable	Mitigate or budget to develop strategy plan
4	3	High Risk	Unacceptable	Mitigate or develop contingency plan
2.-3	2	Low Risk	Acceptable	Ad hoc response from experts at CRPM
1	1	Minimum Risks	Acceptable	Continue to monitor the risk

		Main Risks		**Category Risks**		**Global Risk**		**Risk Magnitude**	**Risk acceptability**
Costs	**Causes**	Risk Code	Risk Value	Risk Code	Risk Value	Risk Code	Risk Value		
Internal	Raw Material	R_cI_1	0.545	**R_cI**	0.59475	**R_c**	0.5952	High Risk	Unacceptable
	Manufacturing	R_cI_2	0.605						
	Design	R_cI_3	0.610						
	Material Handling	R_cI_4	0.700						
External	Sub-contracting	R_cE_1	0.550	**R_cE**	0.5955				
	People	R_cE_2	0.500						
	Environment	R_cE_3	0.680						
	Fluctuation in Exchange rate	R_cE_4	0.830						

		Main Risks		Category Risks		Global Risk		Risk Magnitude	Risk acceptability
Time	**Causes**	Risk Code	Risk Value	Risk Code	Risk Value	Risk Code	Risk Value		
Internal	Raw Material	R_TI_1	0.530						
	Design	R_TI_2	0.605						
	Manufacturing	R_TI_3	0.495	**R_TI**	0.5525				
	Material Handling	R_TI_4	0.600			**R_T**	0.6505	Maximum Risk	Unacceptable
External	Sub-Contracting	R_TE_1	0.680						
	People	R_TE_2	0.700	**R_TE**	0.675				
	Environment	R_TE_3	0.680						

	Risks Magnitude	**Risk Acceptability**
0.61 – 1	Maximum Risk	Unacceptable
0.41 - 0.6	High Risk	Unacceptable
0.21 - 0.4	Low Risk	Acceptable
0 - 0.2	Minimum Risks	Acceptable